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(54) **SURGICAL INSTRUMENTS FOR LAPAROSCOPIC ASPIRATION AND RETRACTION**

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(51) **Int. Cl.**

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A61B 17/00	(2006.01)
A61B 17/22	(2006.01)
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(52) **U.S. Cl.**

CPC ***A61B 17/00234*** (2013.01); ***A61B 17/0218*** (2013.01); *A61B 17/0057* (2013.01); *A61B 2017/00349* (2013.01); *A61B 2017/00637* (2013.01); *A61B 2017/00986* (2013.01); *A61B 2017/22054* (2013.01); *A61B 2017/22069* (2013.01); *A61B 2017/3488* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/0218; A61B 2017/00349; A61B 2017/00637; A61B 2017/00986; A61B 2017/22051; A61B 2017/22069; A61B 2017/348–2017/3488

USPC 600/201–249; 606/246–279

See application file for complete search history.

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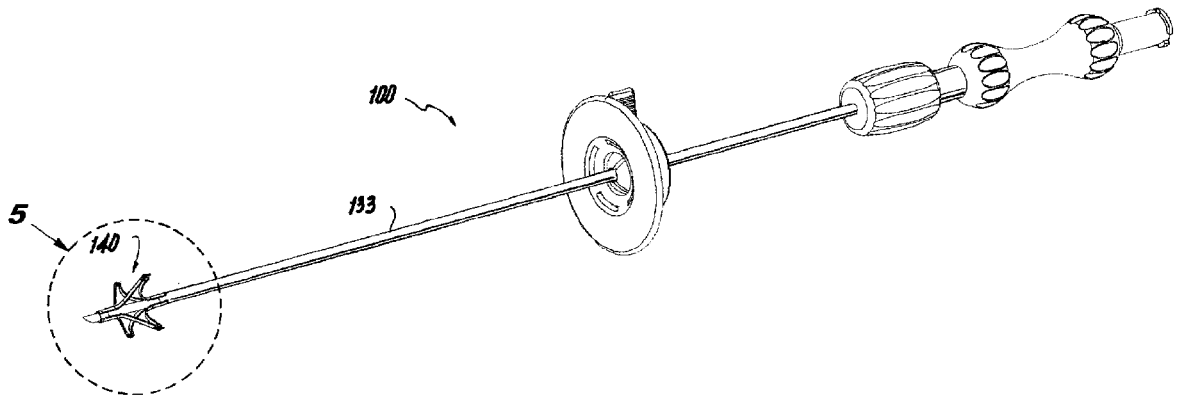
(57) **ABSTRACT**

Various surgical instruments for laparoscopic procedures are provided for aspirating and retracting a hollow organ such as a gallbladder. The surgical instruments include a needle body and an anchor coupled to the needle body. The anchor is adapted and configured for engaging and retracting the hollow organ, and can be held and deployed from within the needle body or from an outside surface of the needle body. The needle body defines an aperture for permitting aspiration of contents of the hollow organ.

34 Claims, 29 Drawing Sheets



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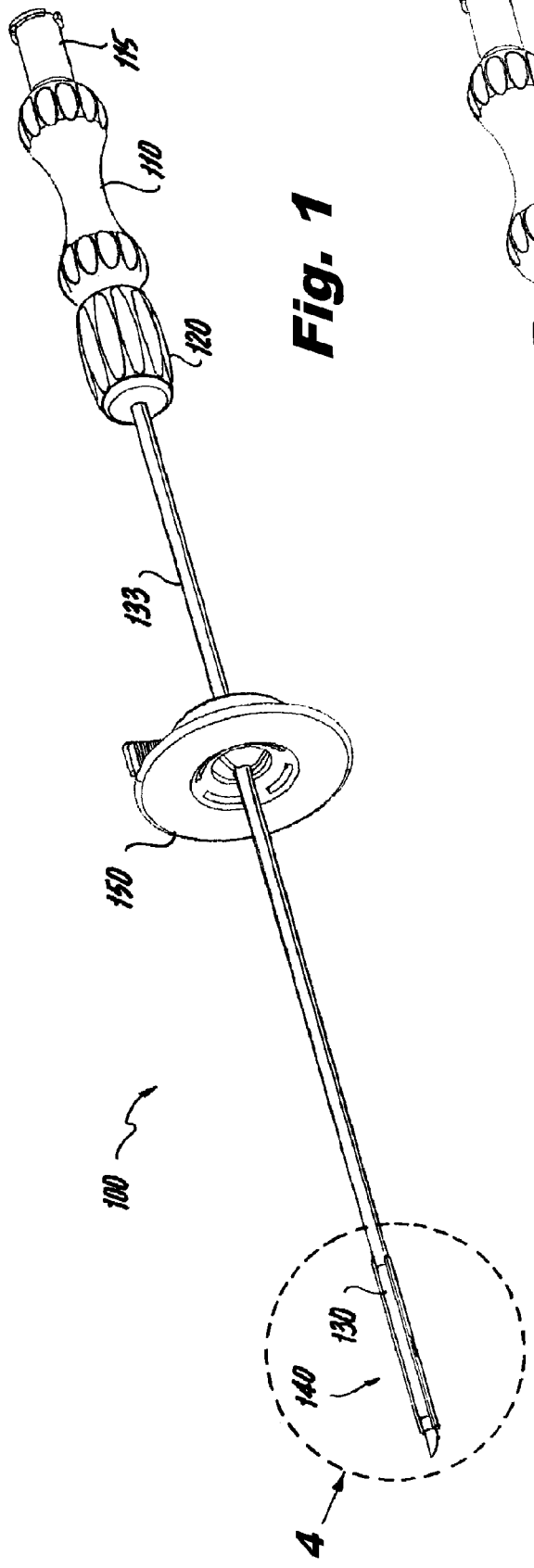

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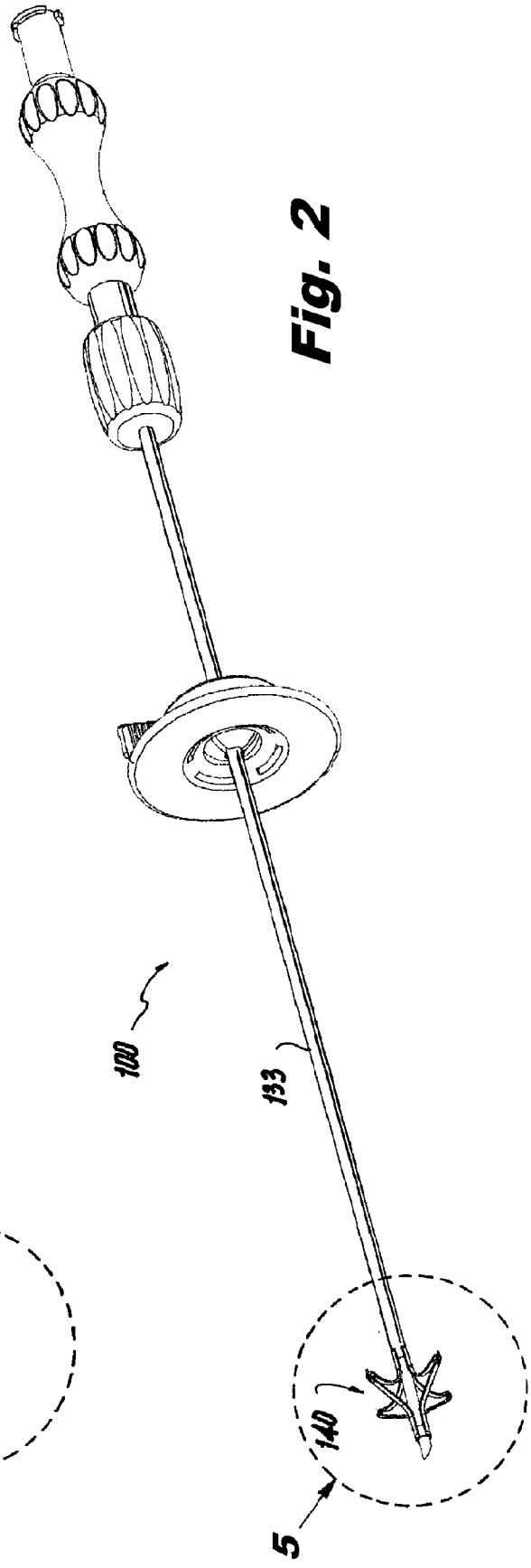

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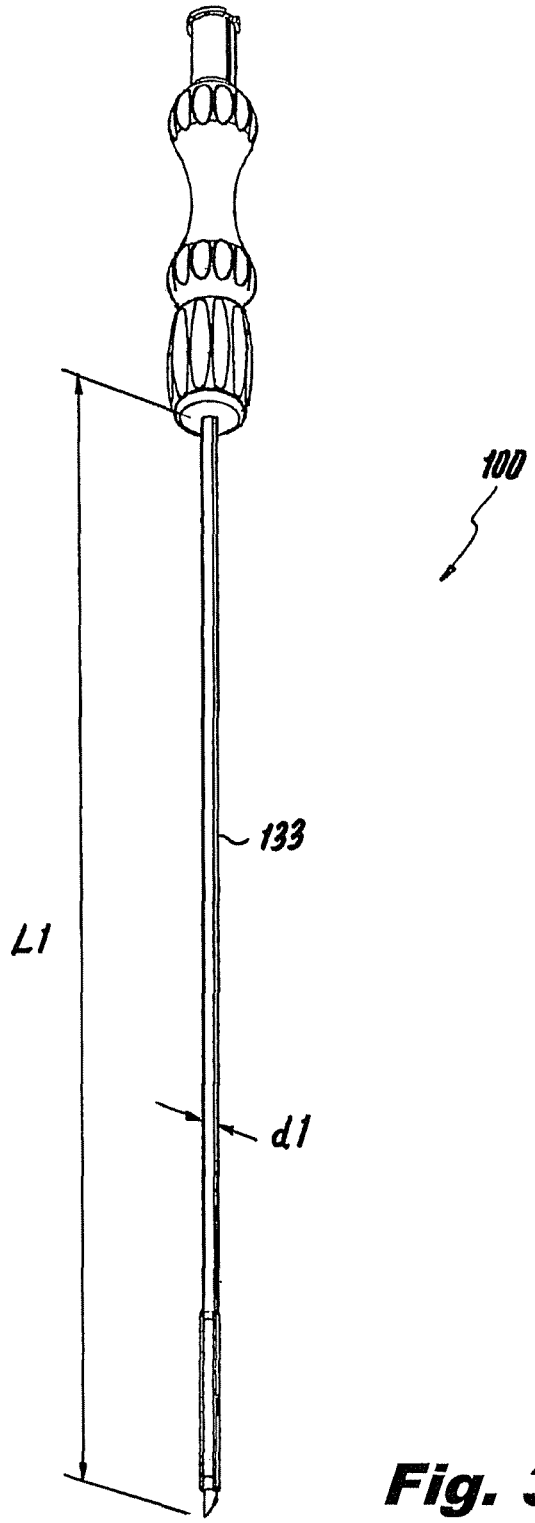
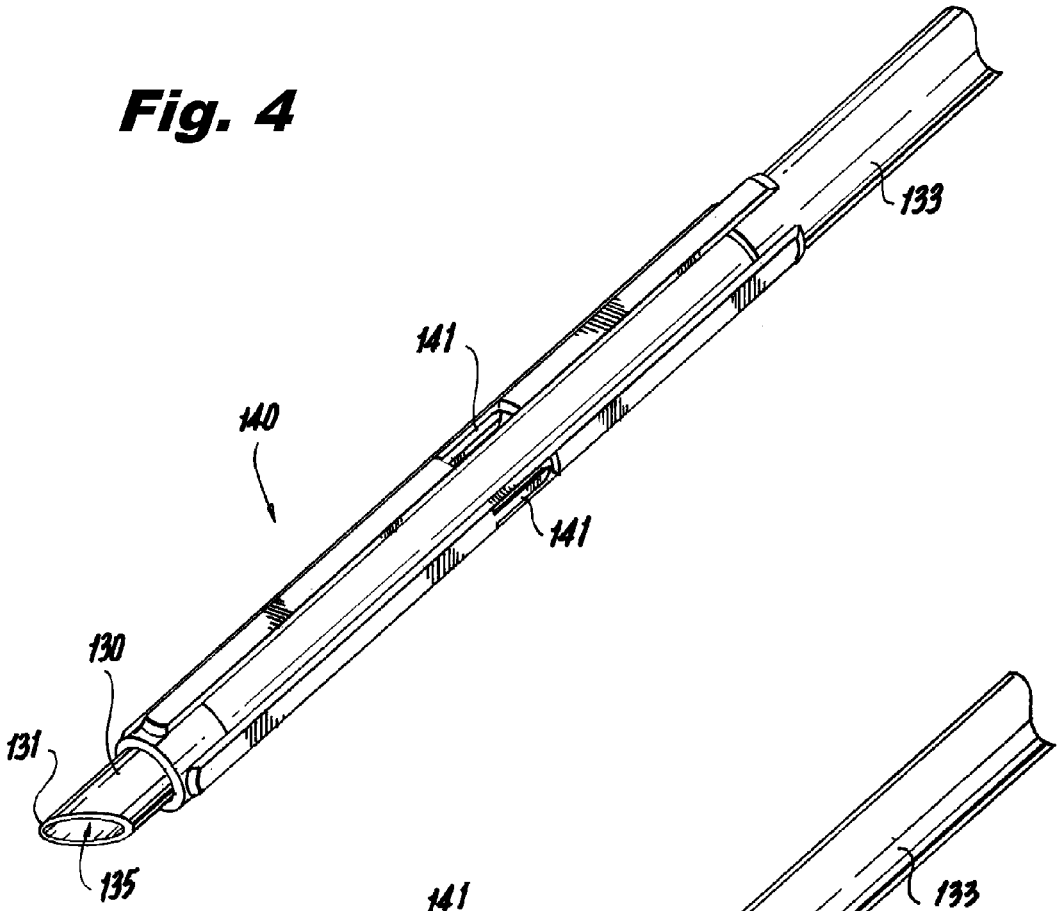


Fig. 3

Fig. 4



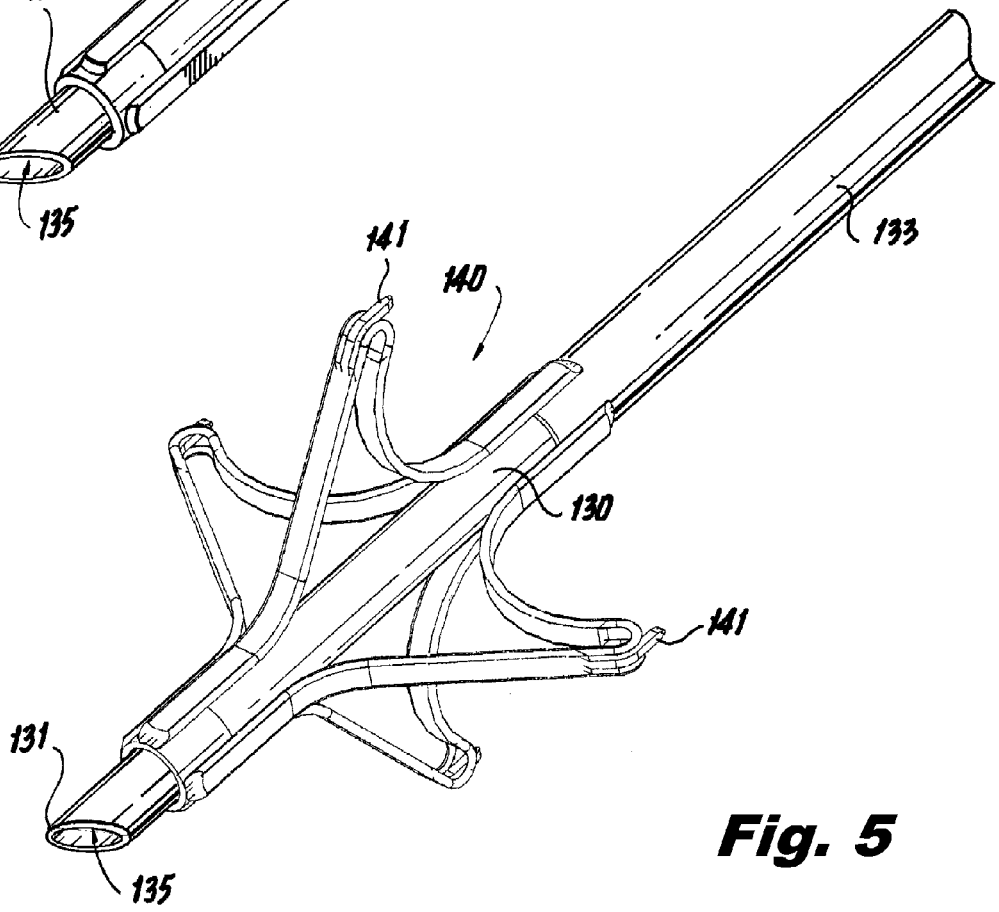
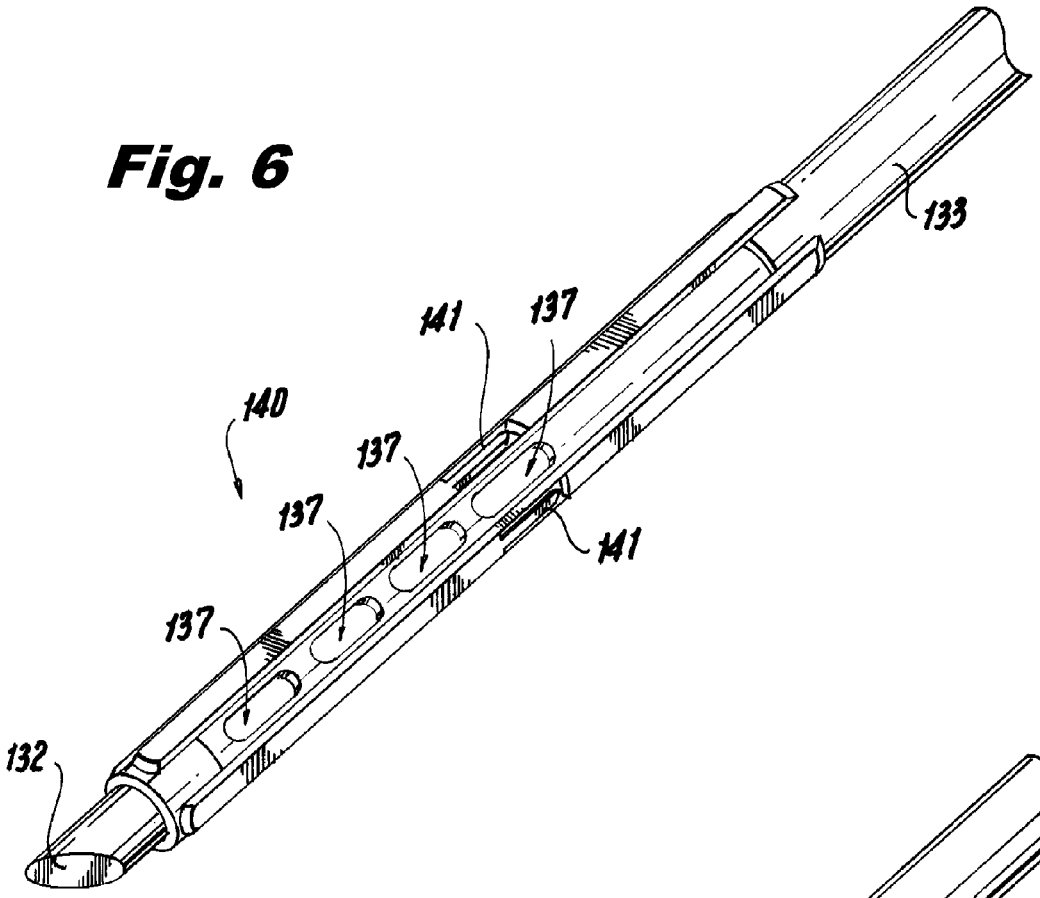
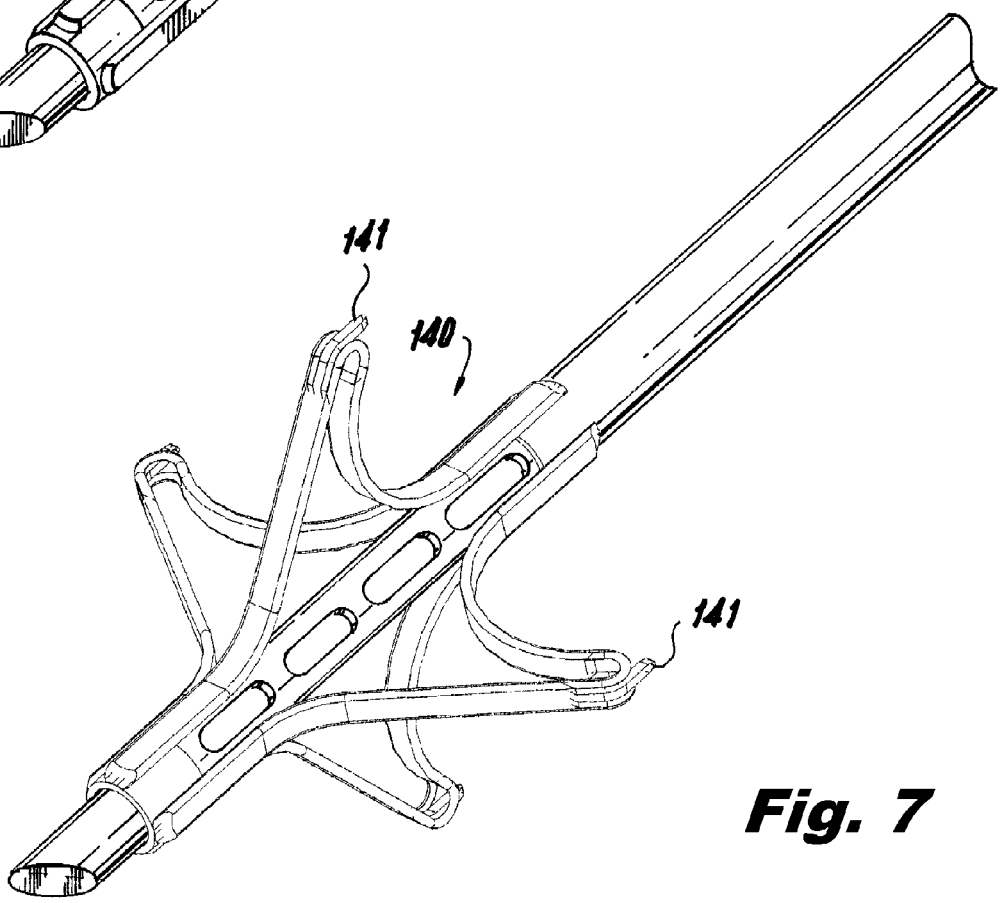


Fig. 5

Fig. 6





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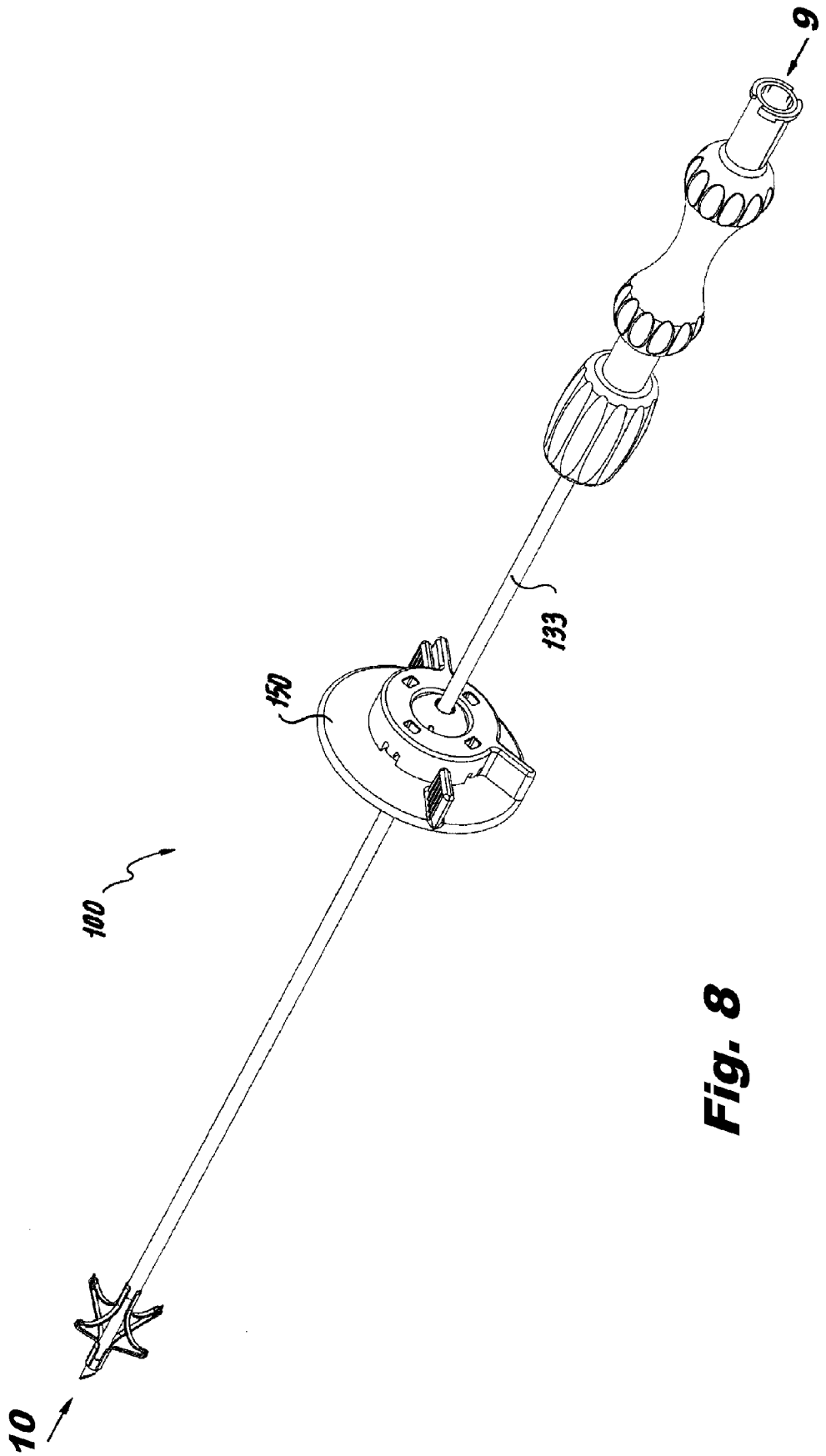

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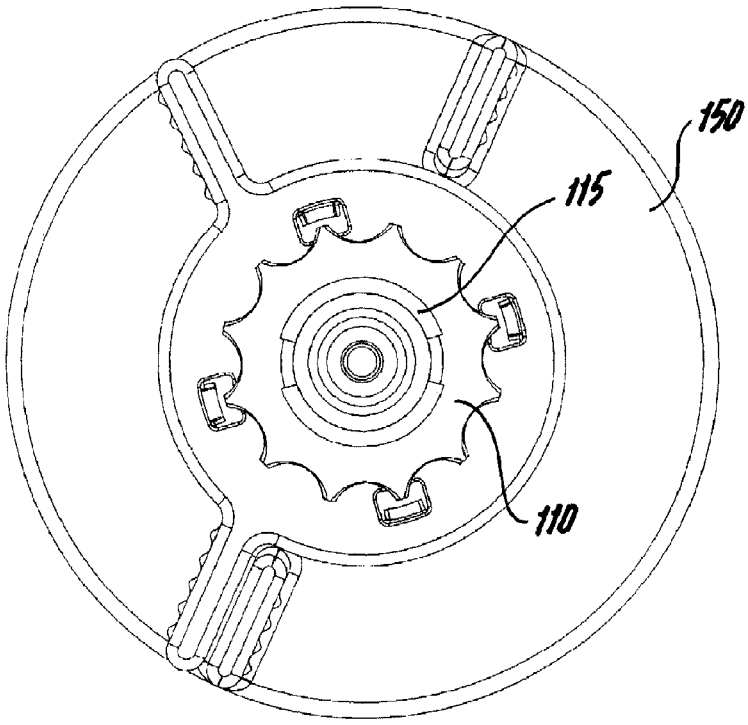

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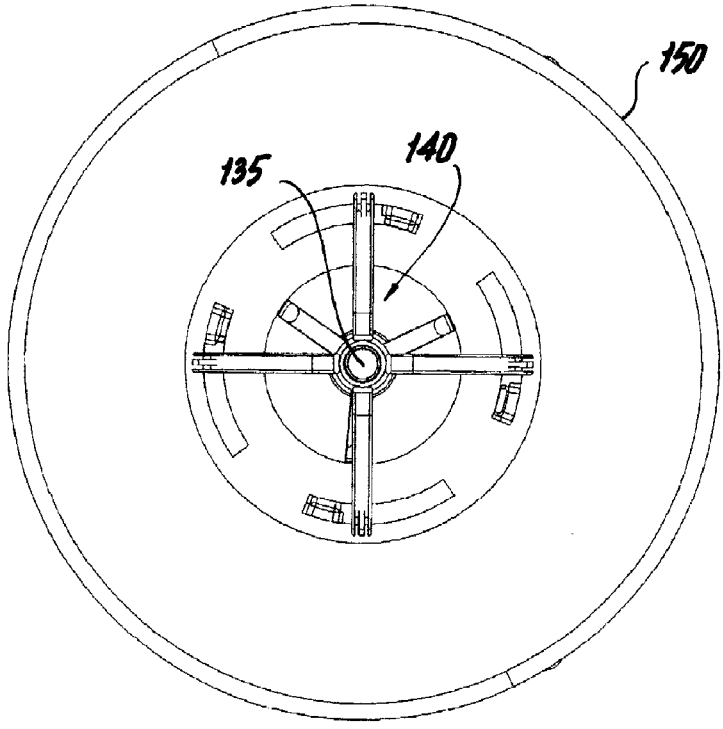
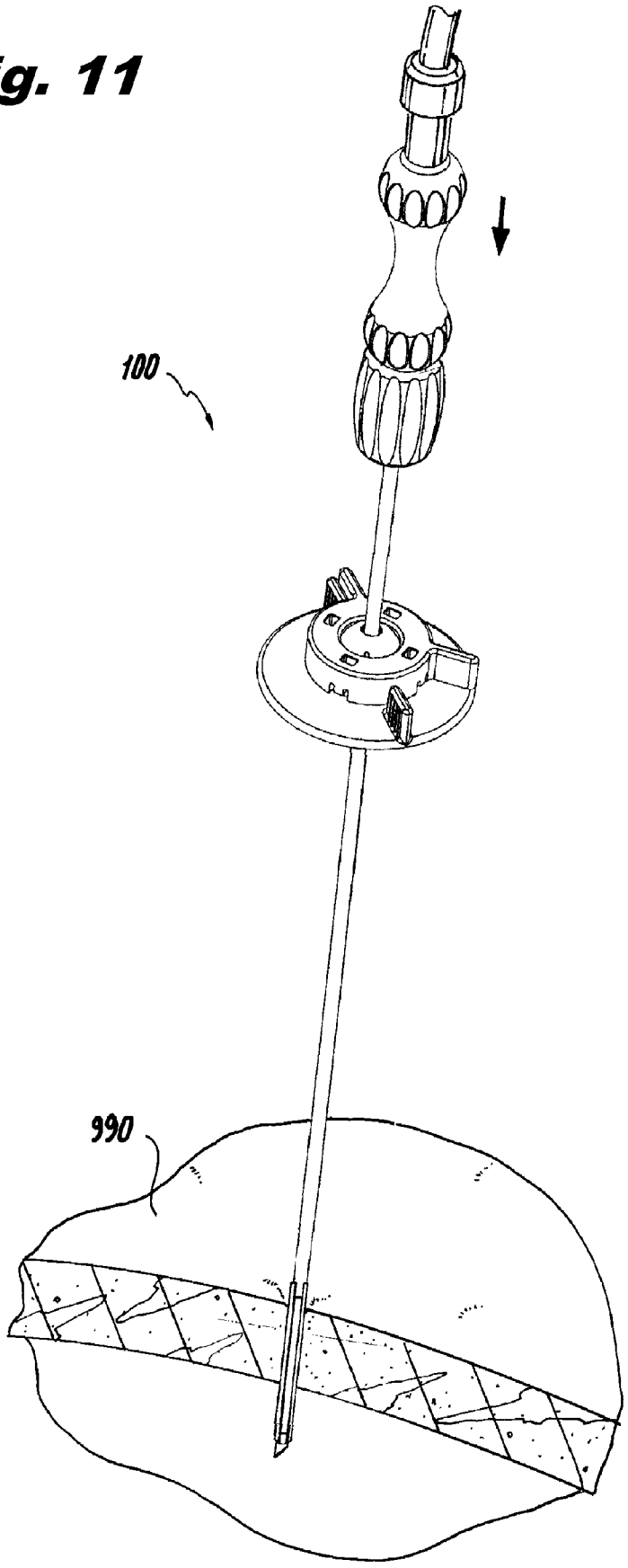


Fig. 10

Fig. 11



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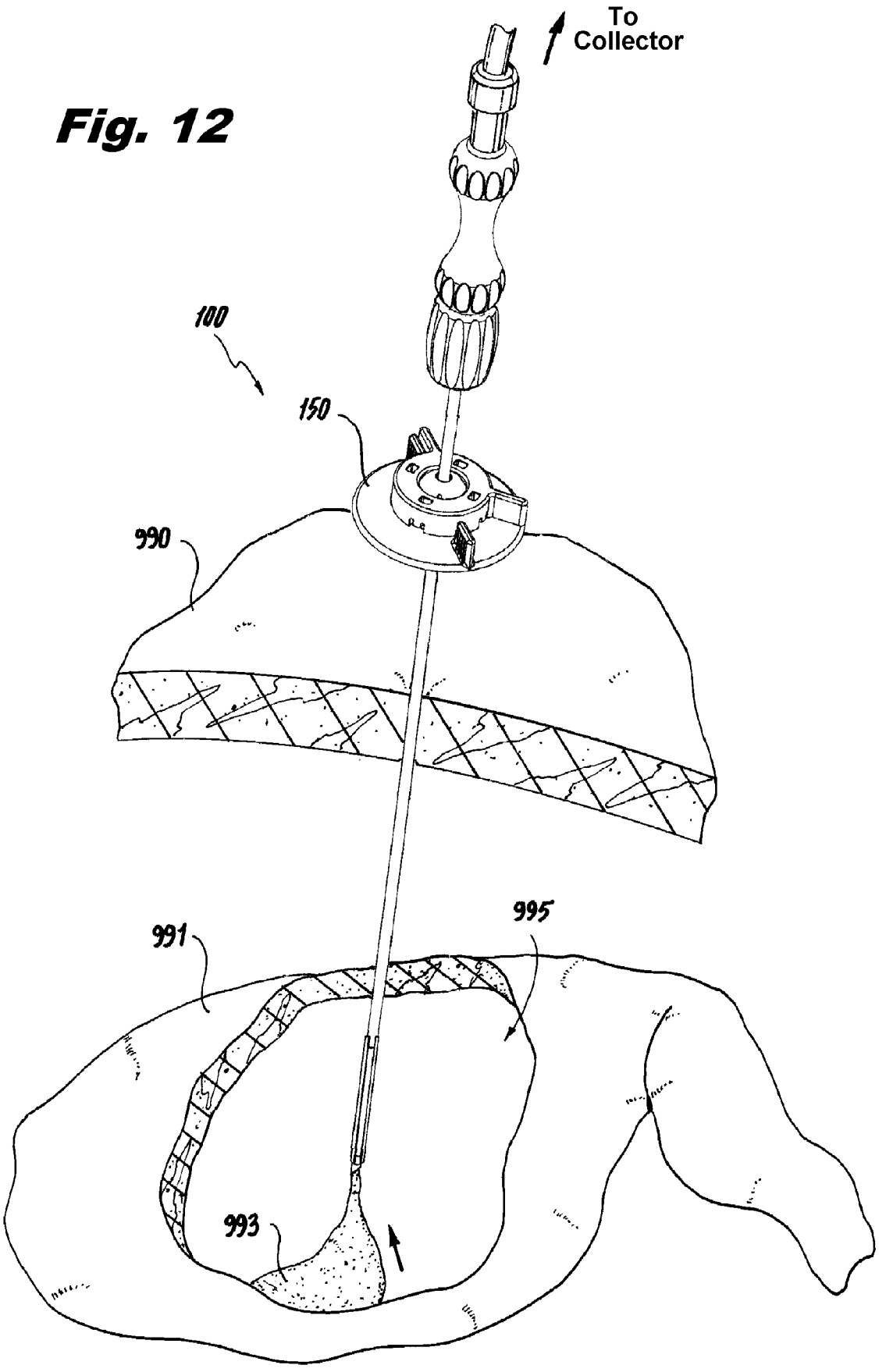

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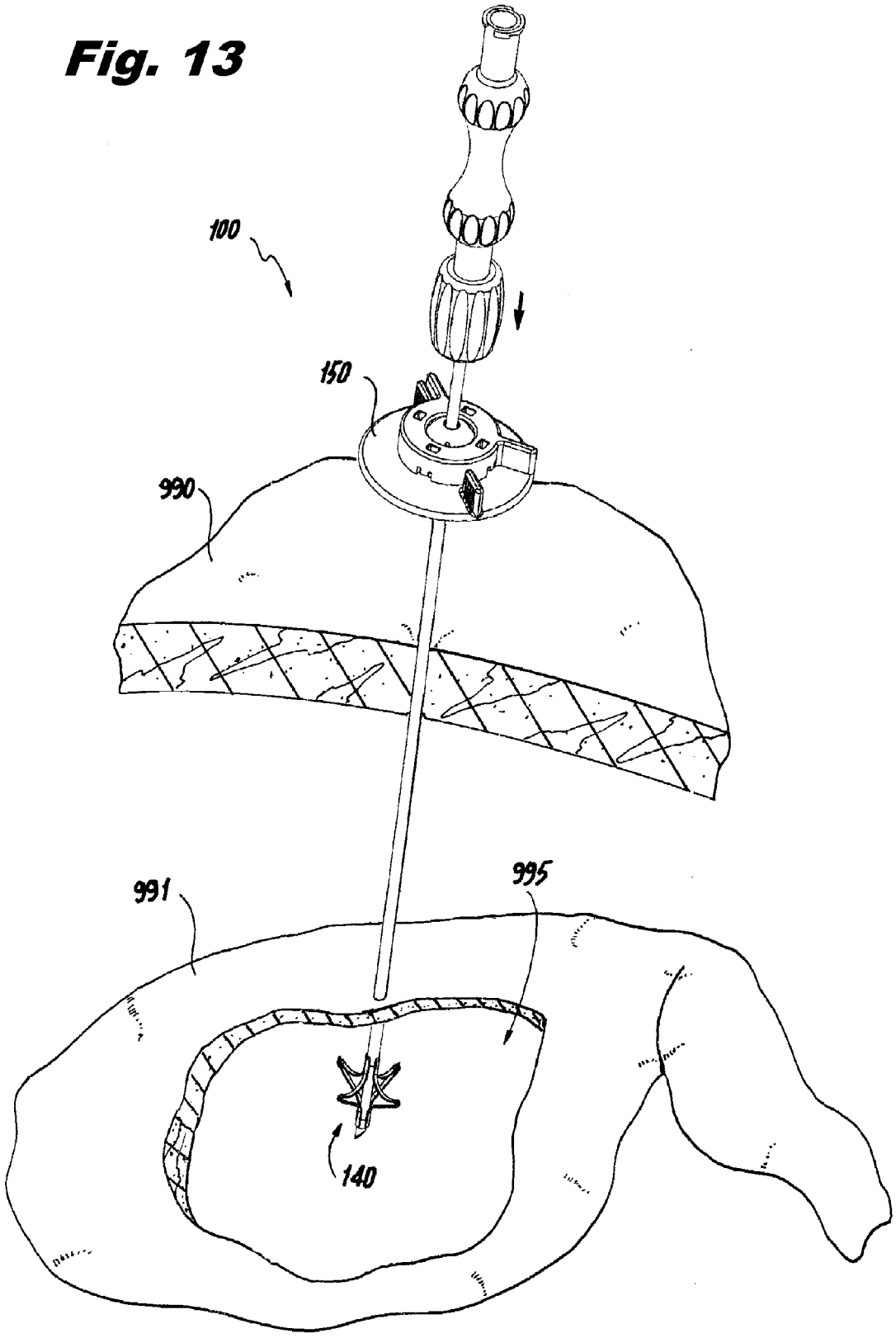

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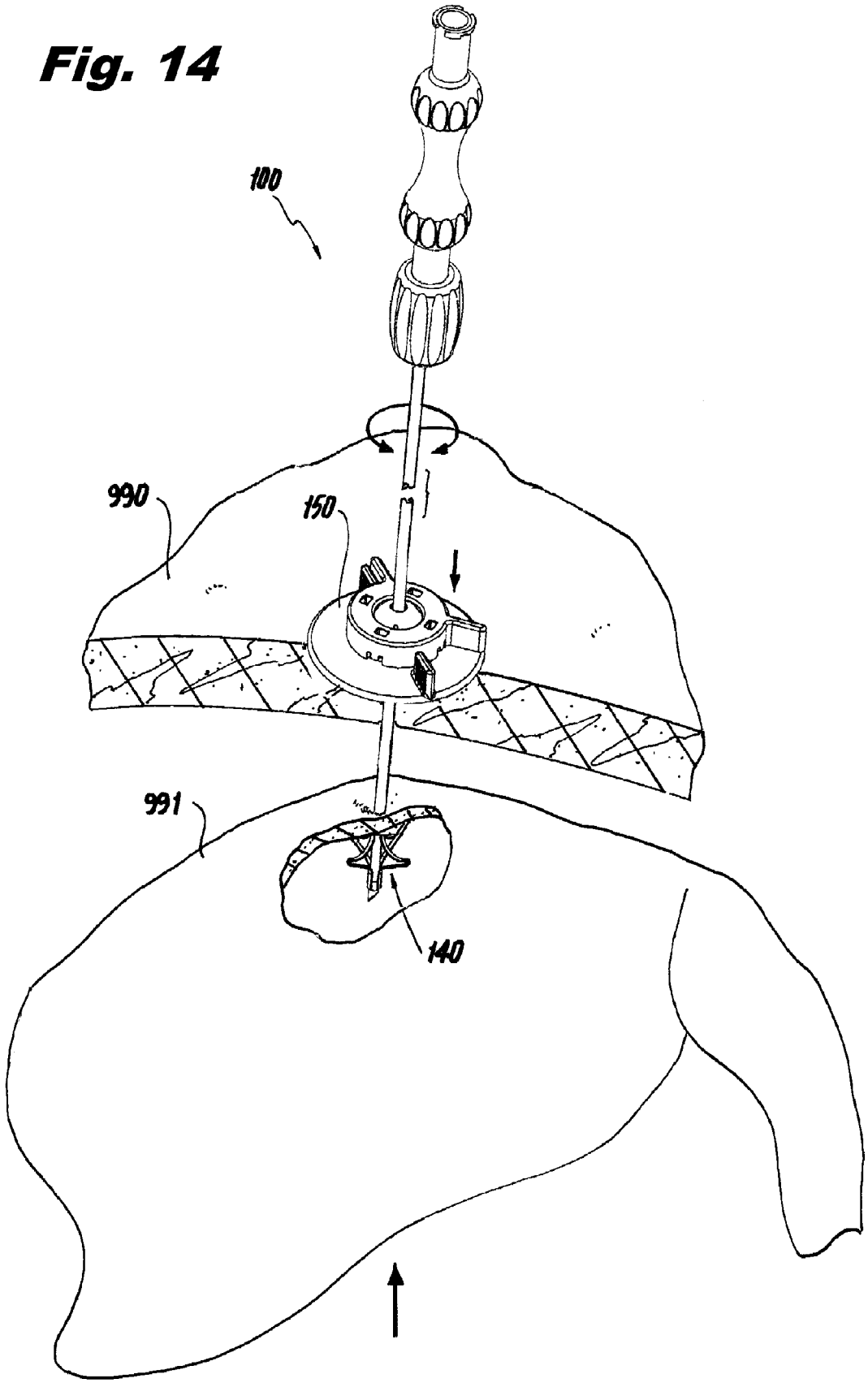

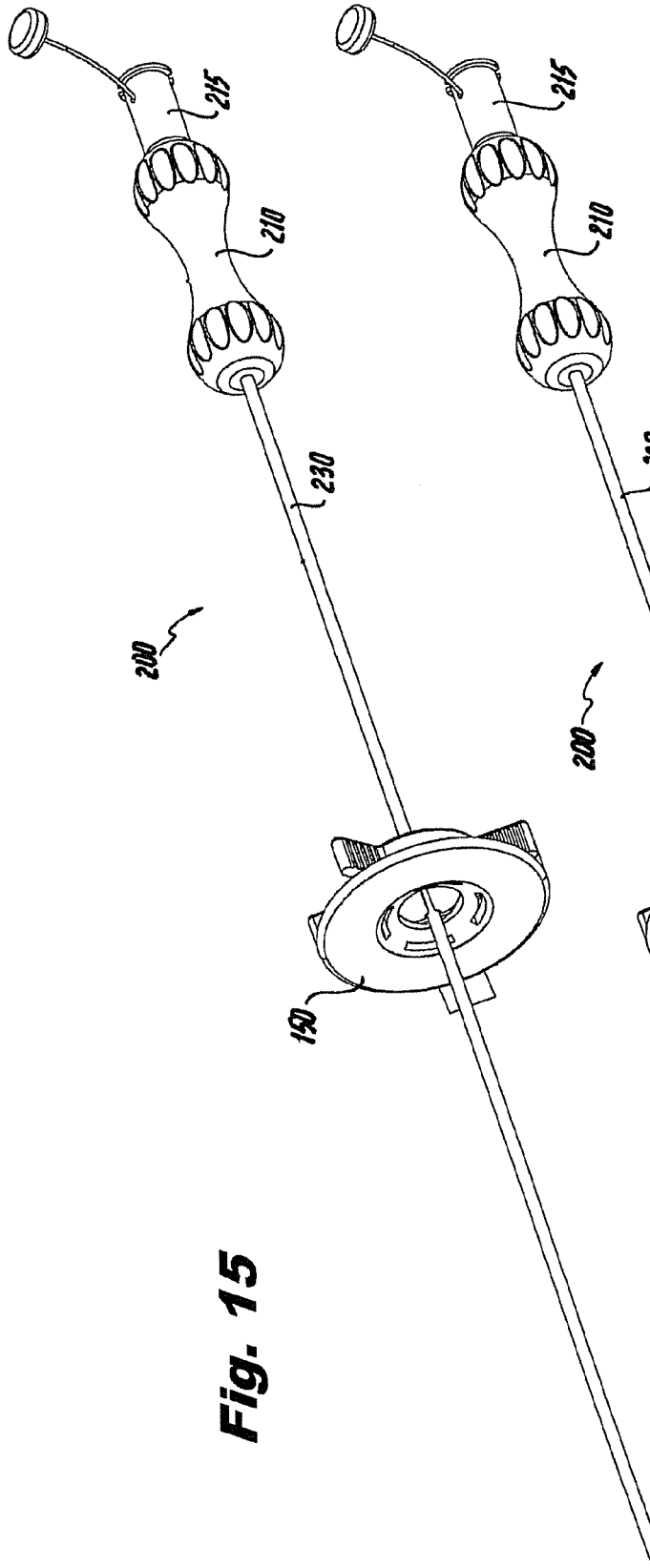

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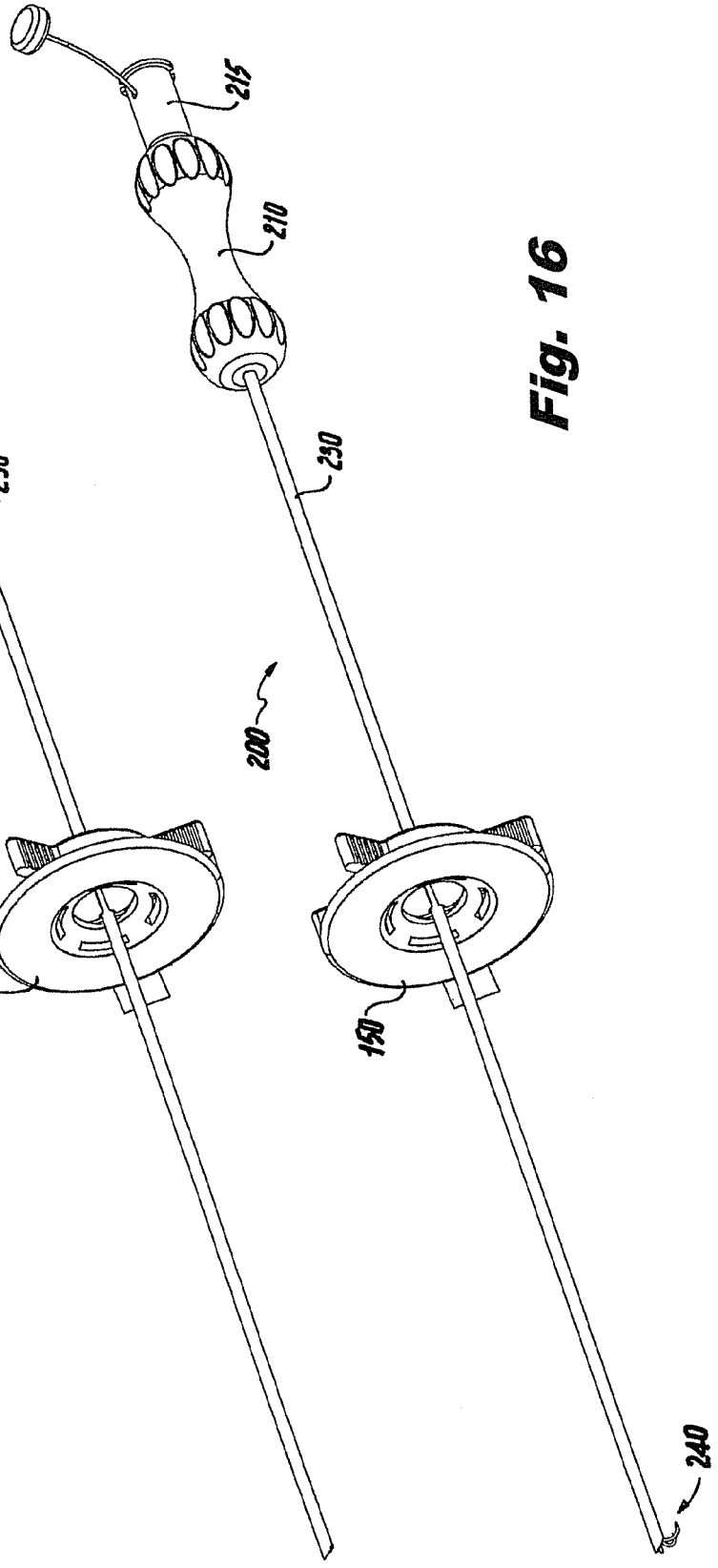
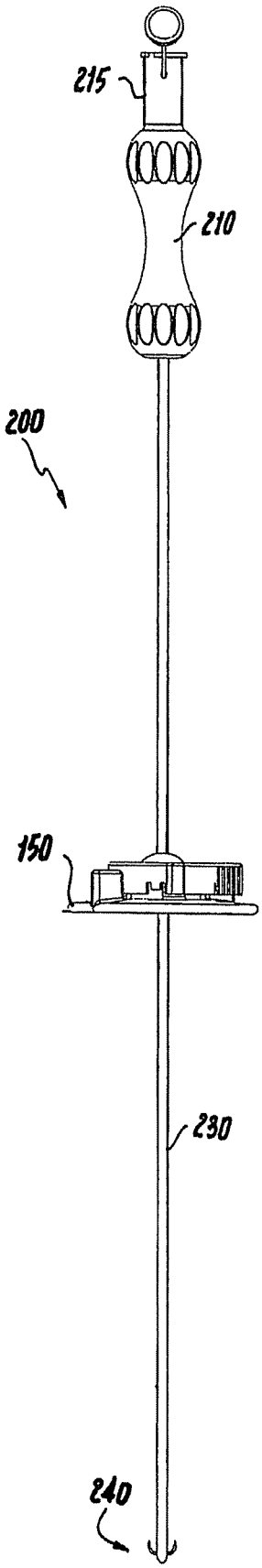
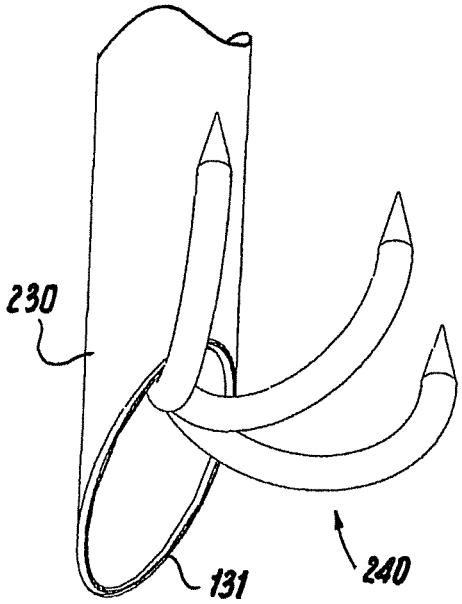


Fig. 16

Fig. 17





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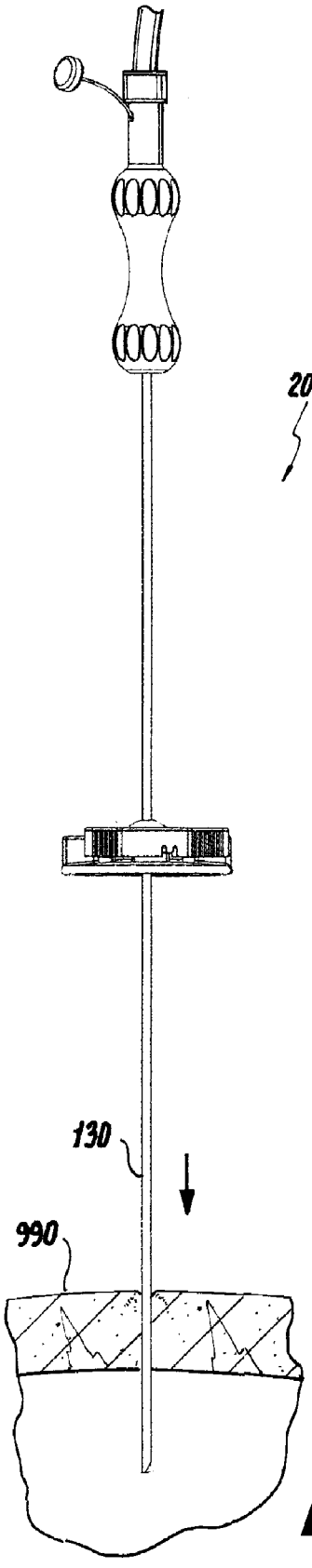


Fig. 19

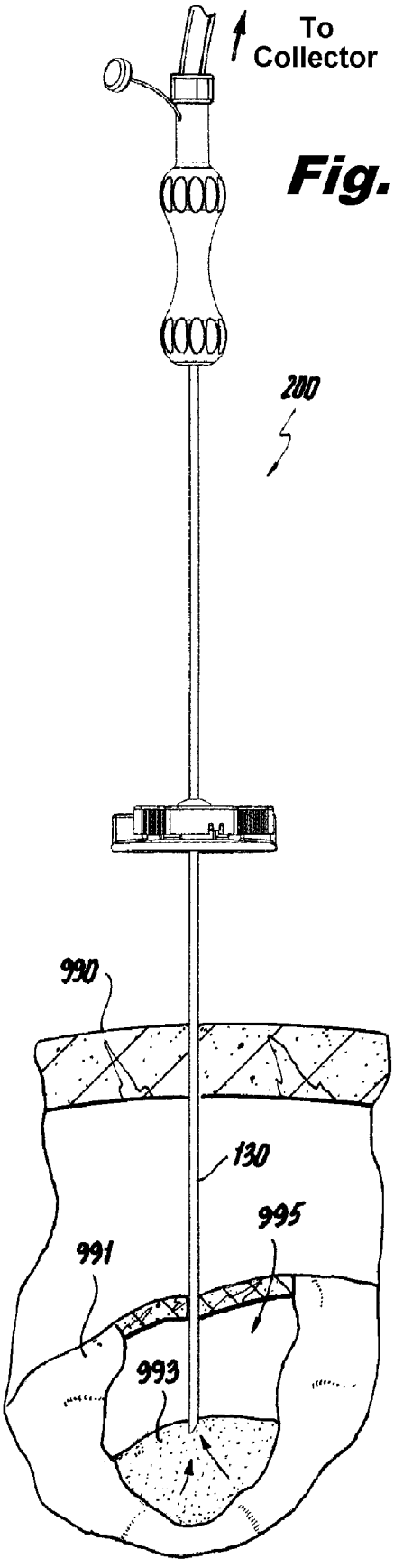


Fig. 20

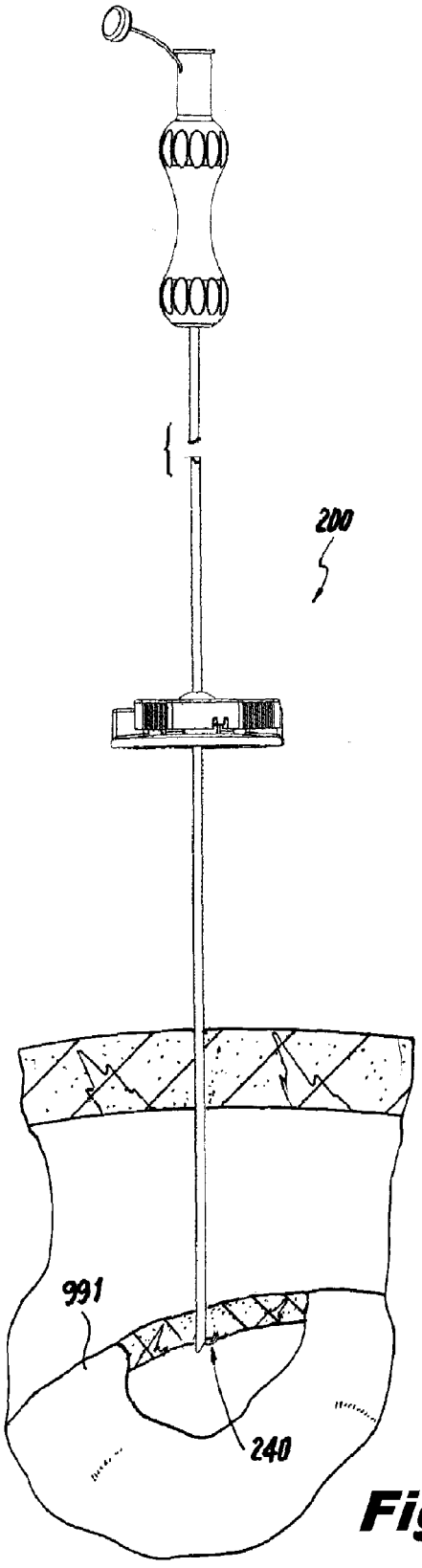


Fig. 21

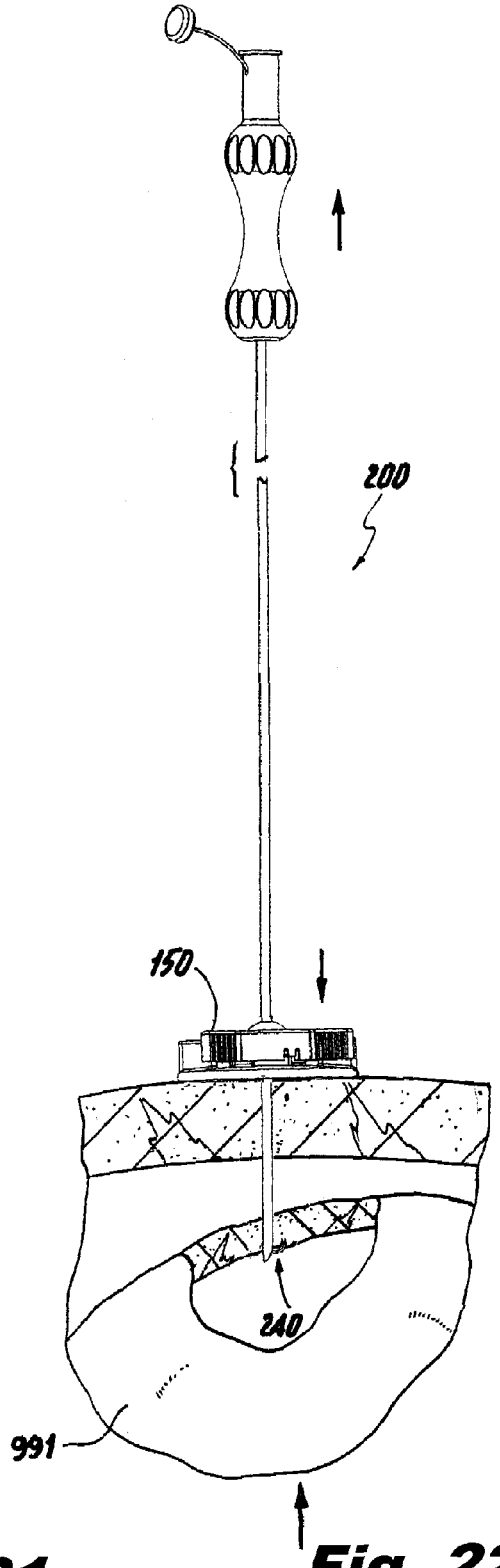


Fig. 22

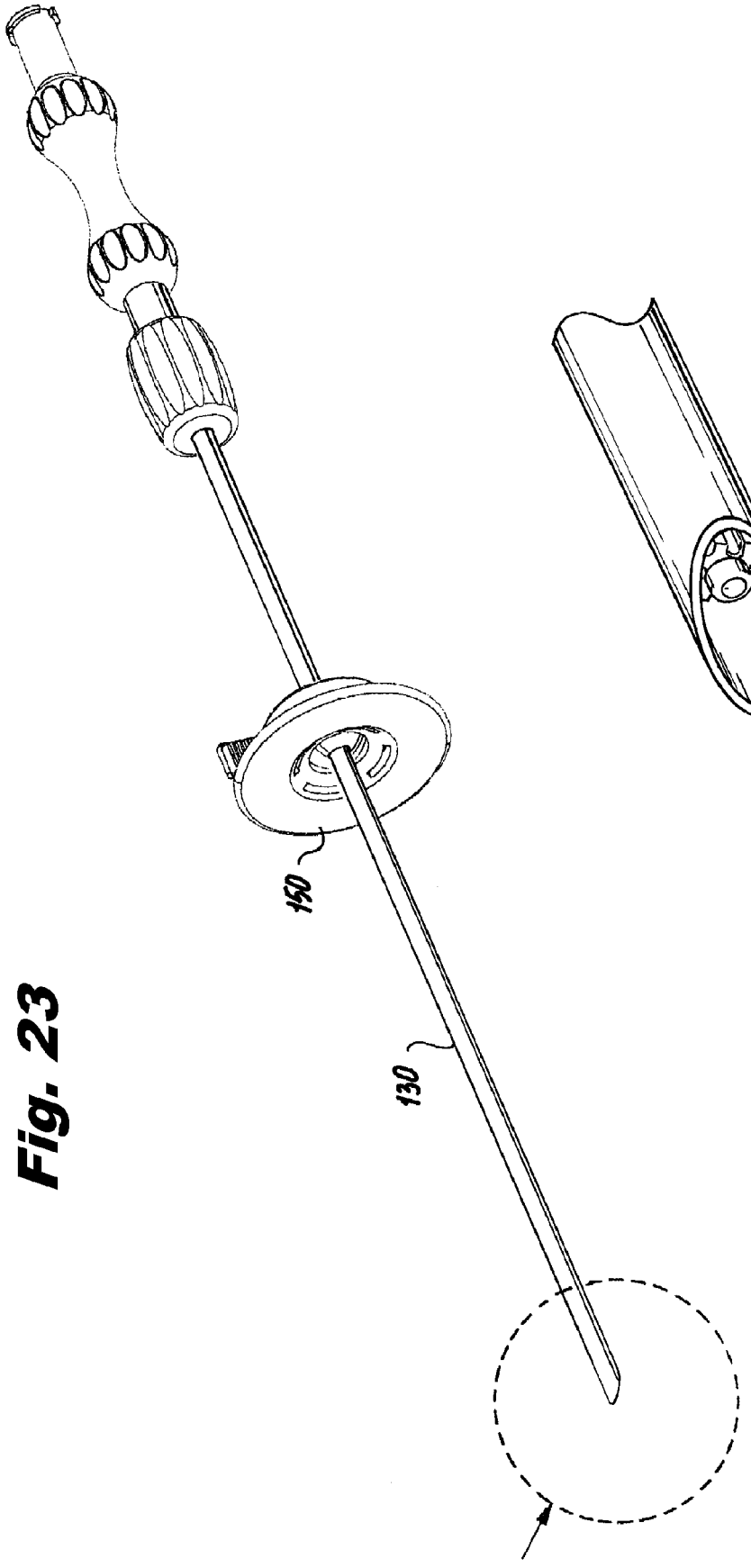
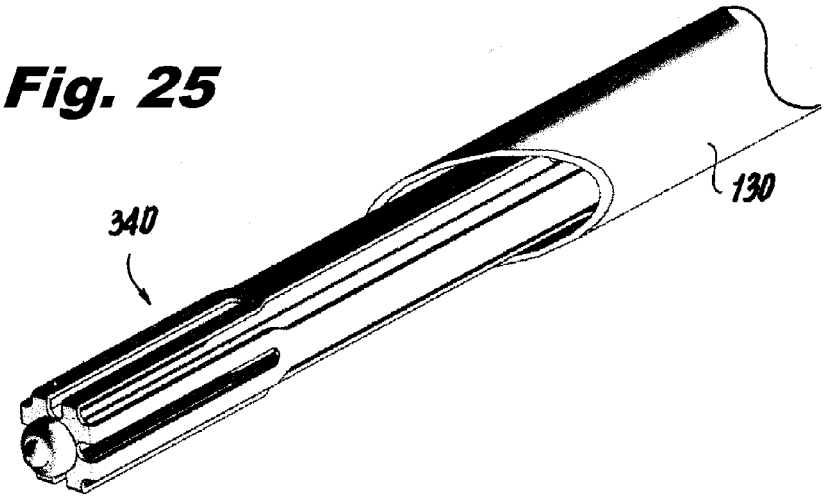


Fig. 23

Fig. 24

Fig. 25



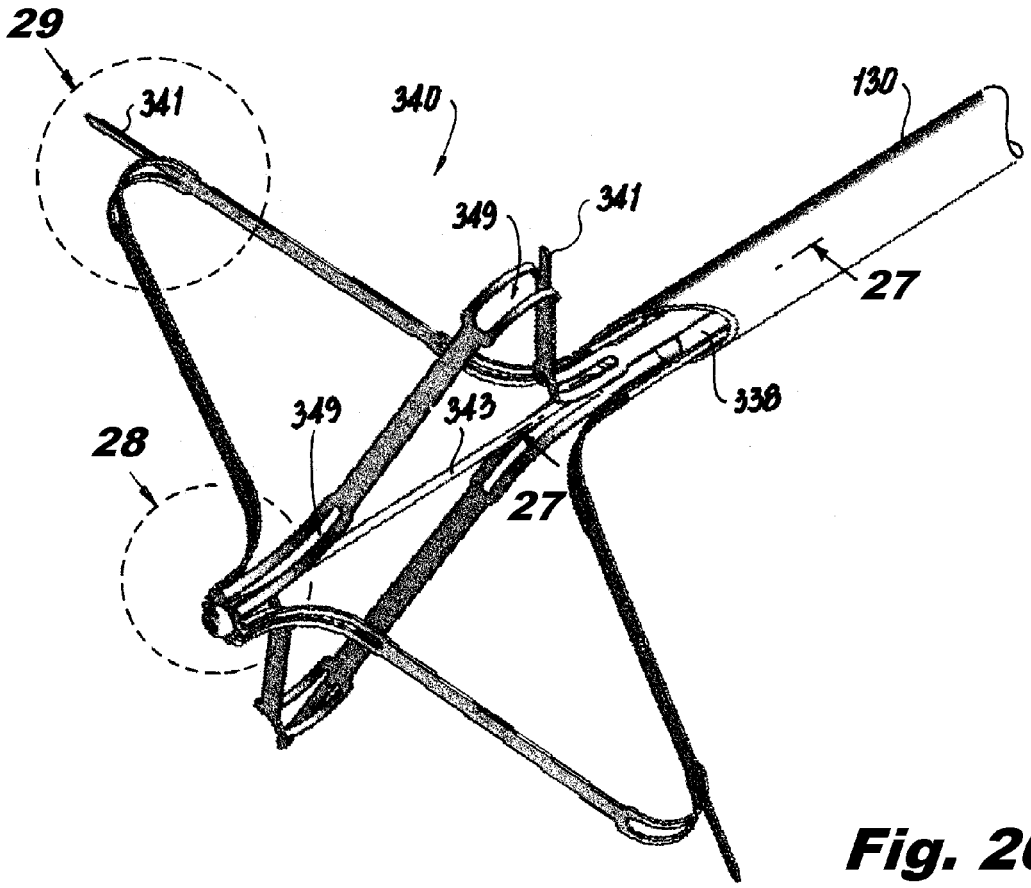
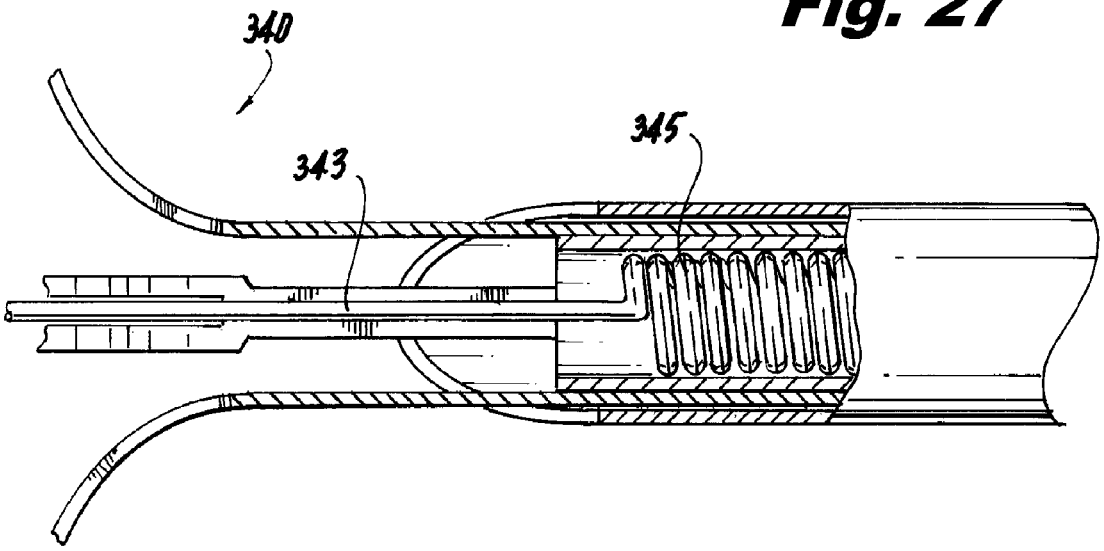


Fig. 26

Fig. 27



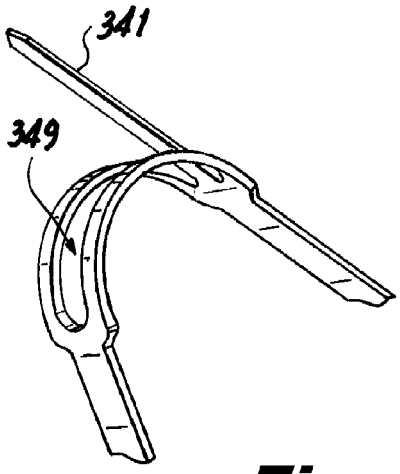


Fig. 28

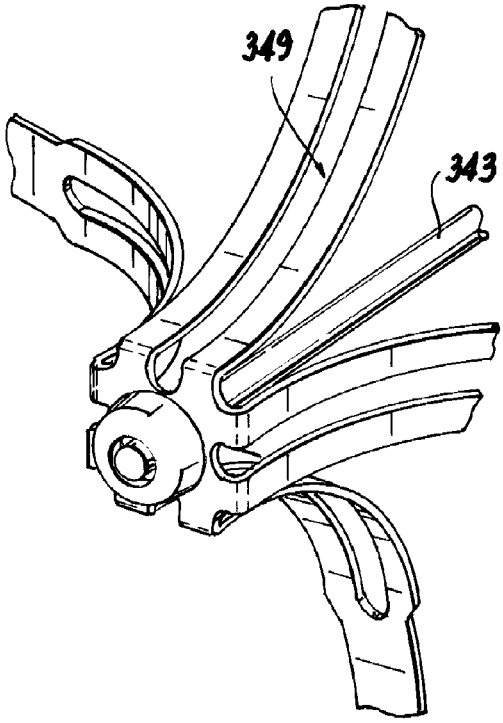
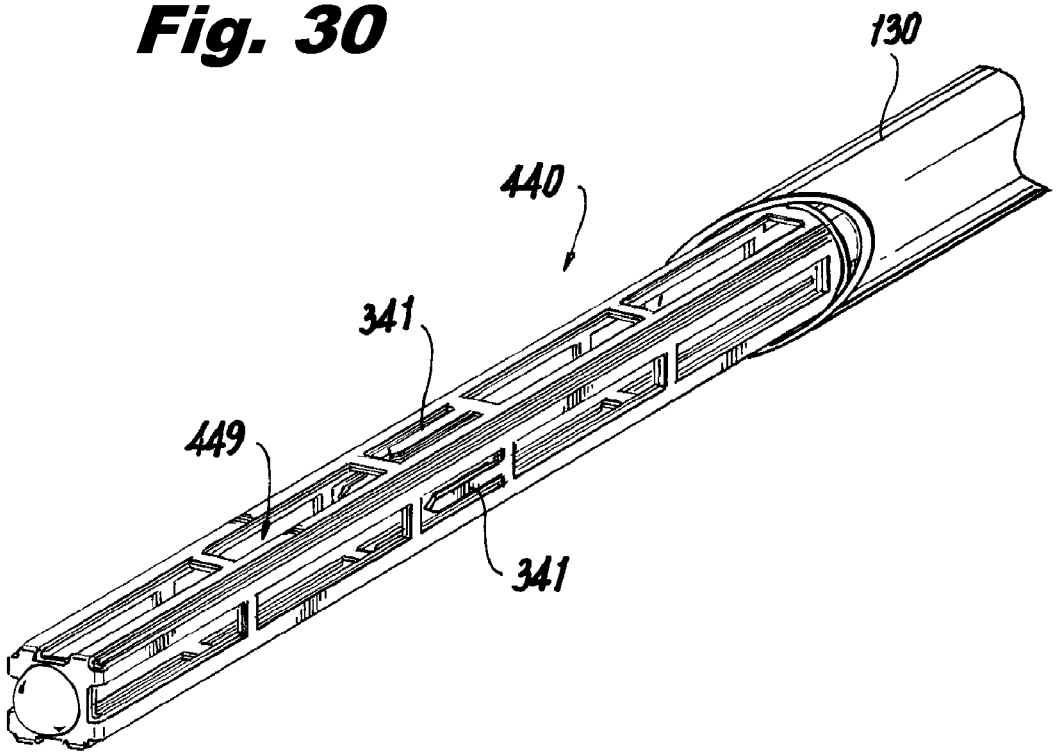


Fig. 29

Fig. 30



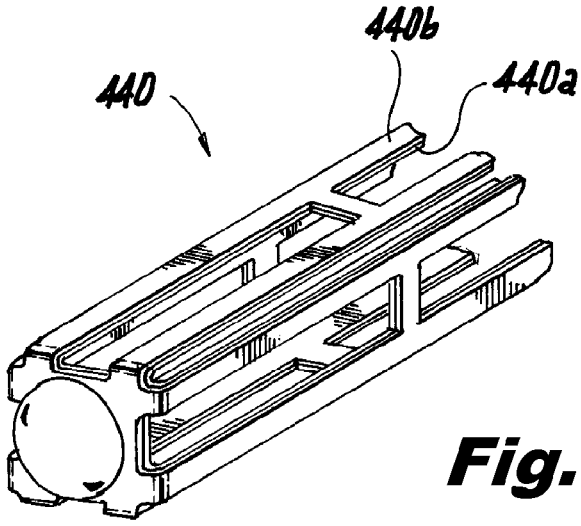


Fig. 31

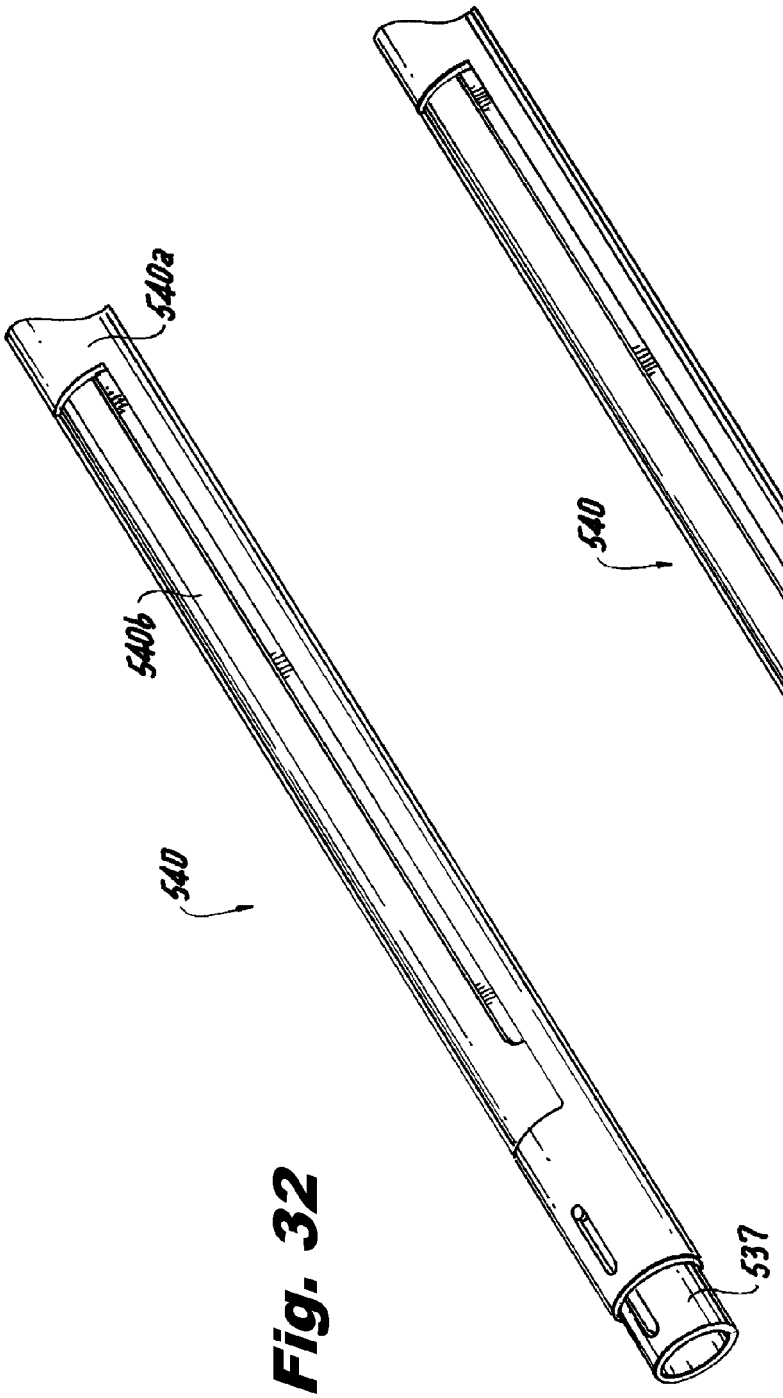


Fig. 32

Fig. 33

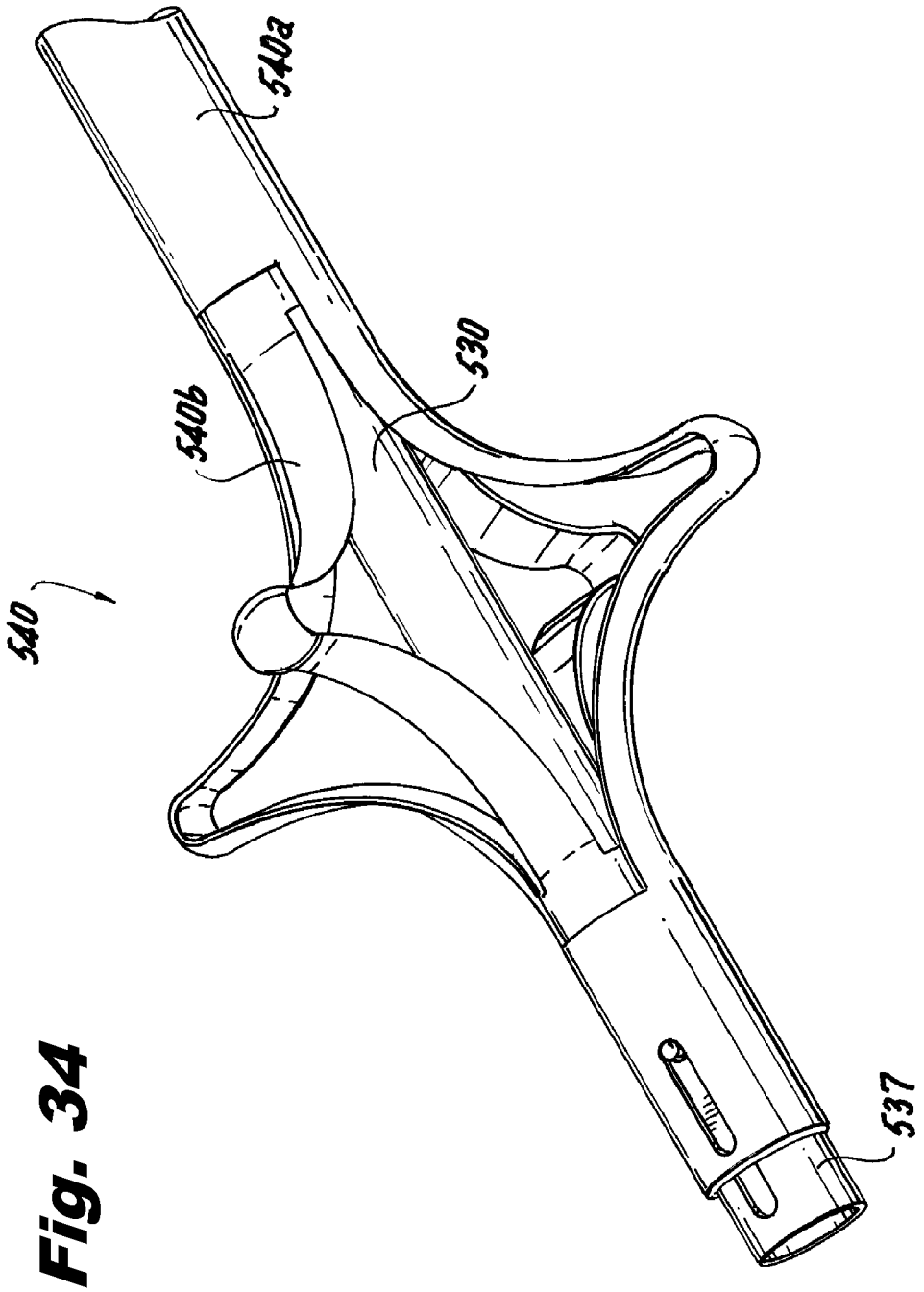


Fig. 34

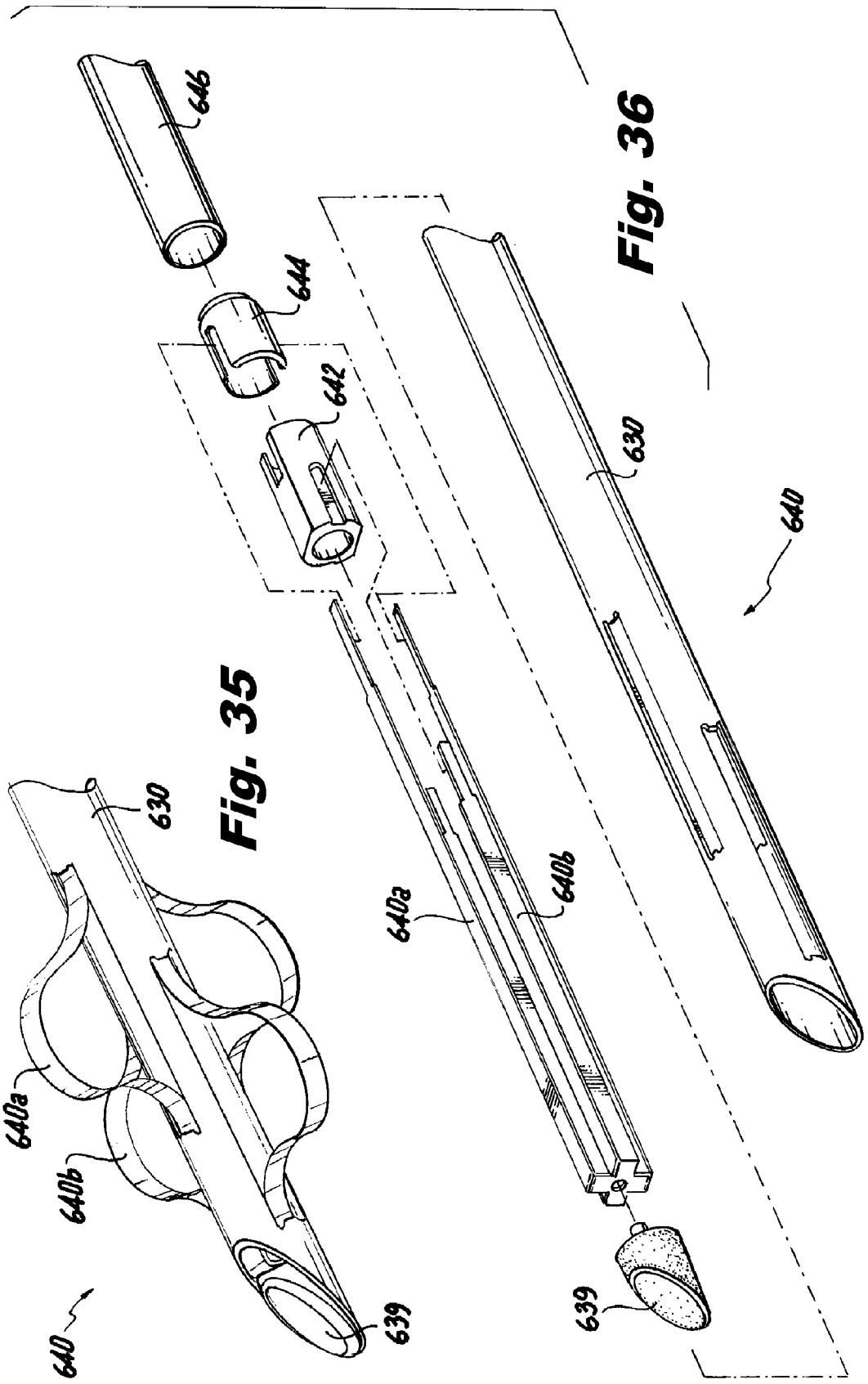


Fig. 35

Fig. 36

Fig. 37

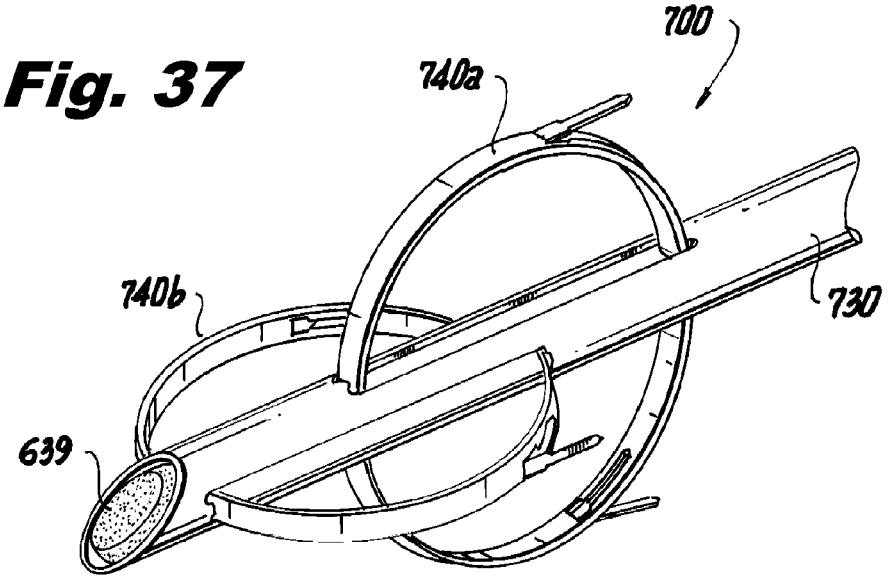


Fig. 38

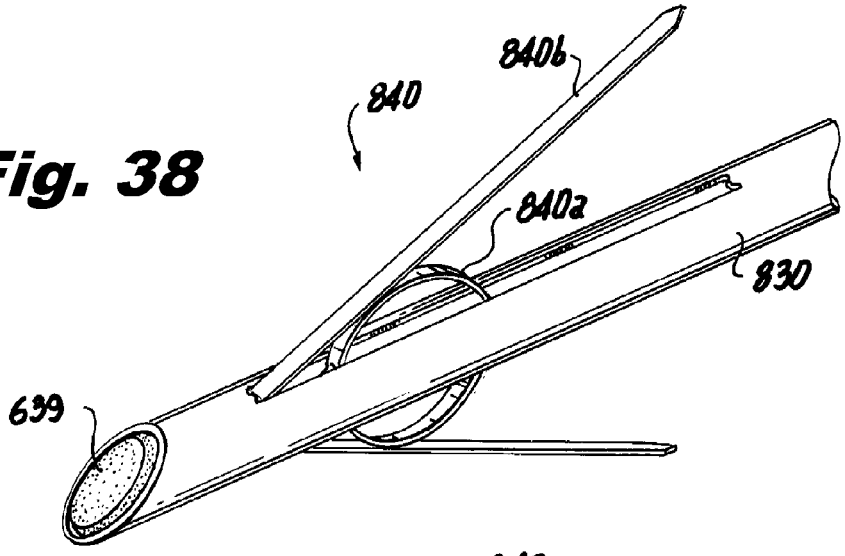


Fig. 39

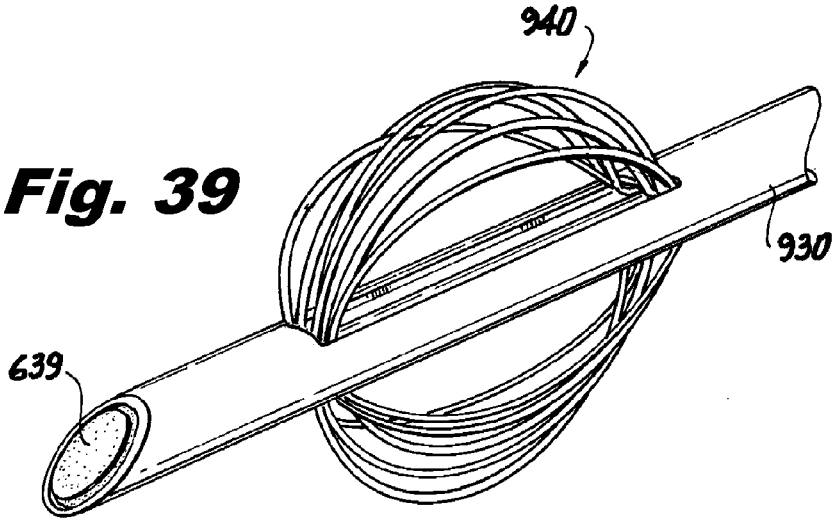


Fig. 40

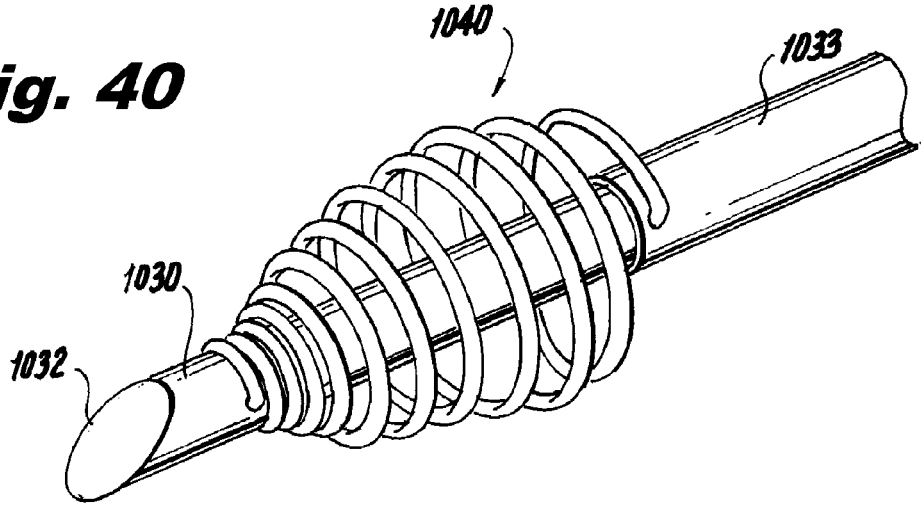


Fig. 41

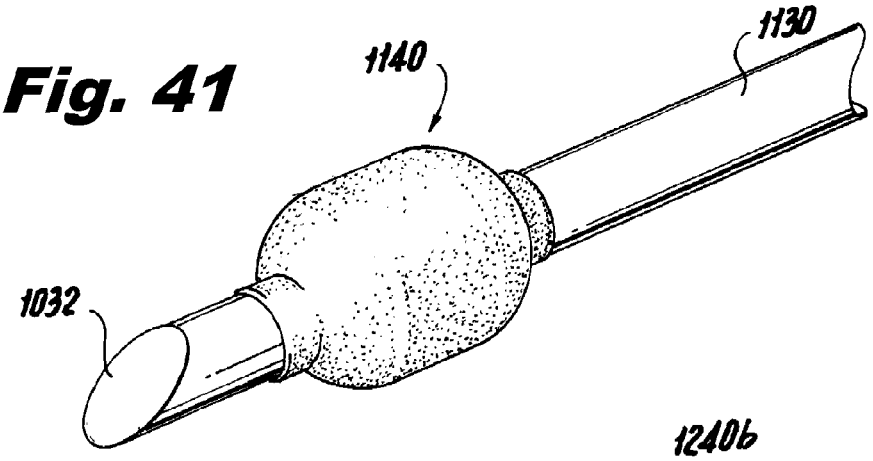
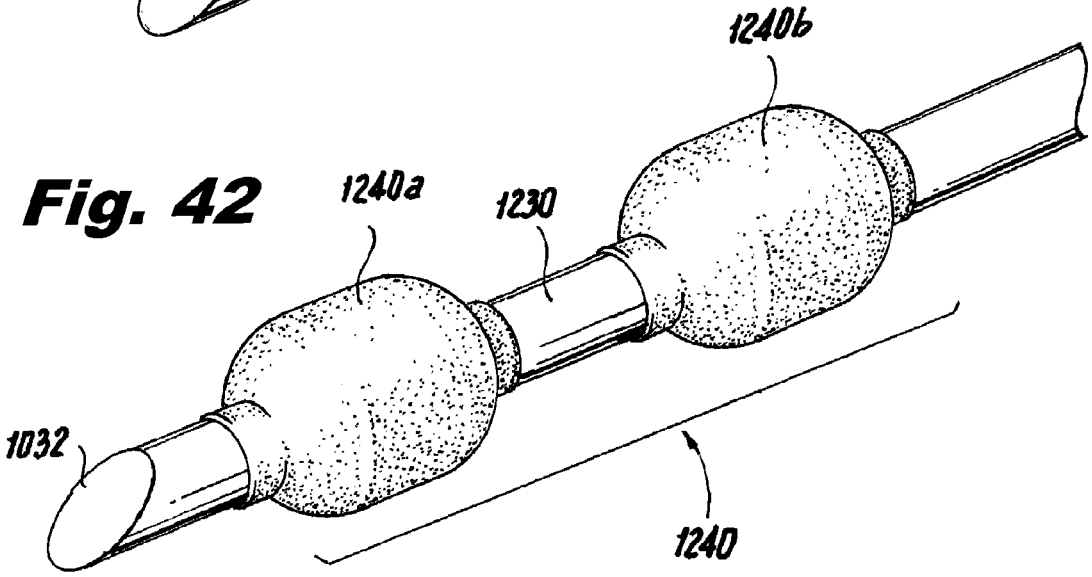


Fig. 42



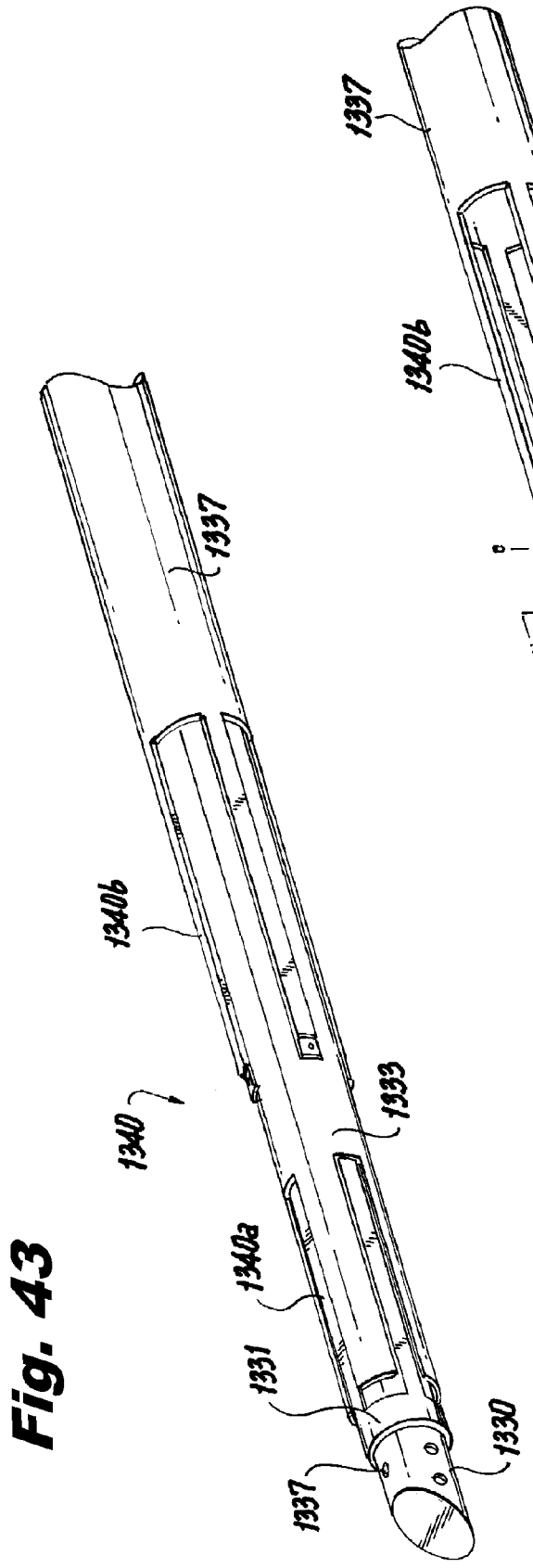

1337
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Fig. 43

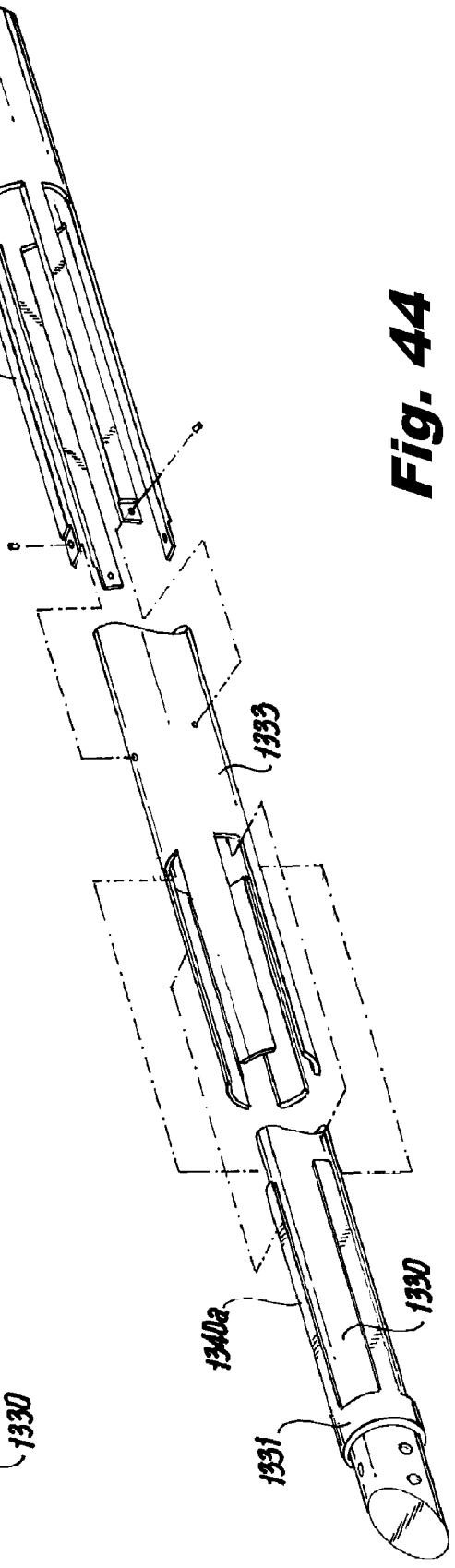
1337
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Fig. 44

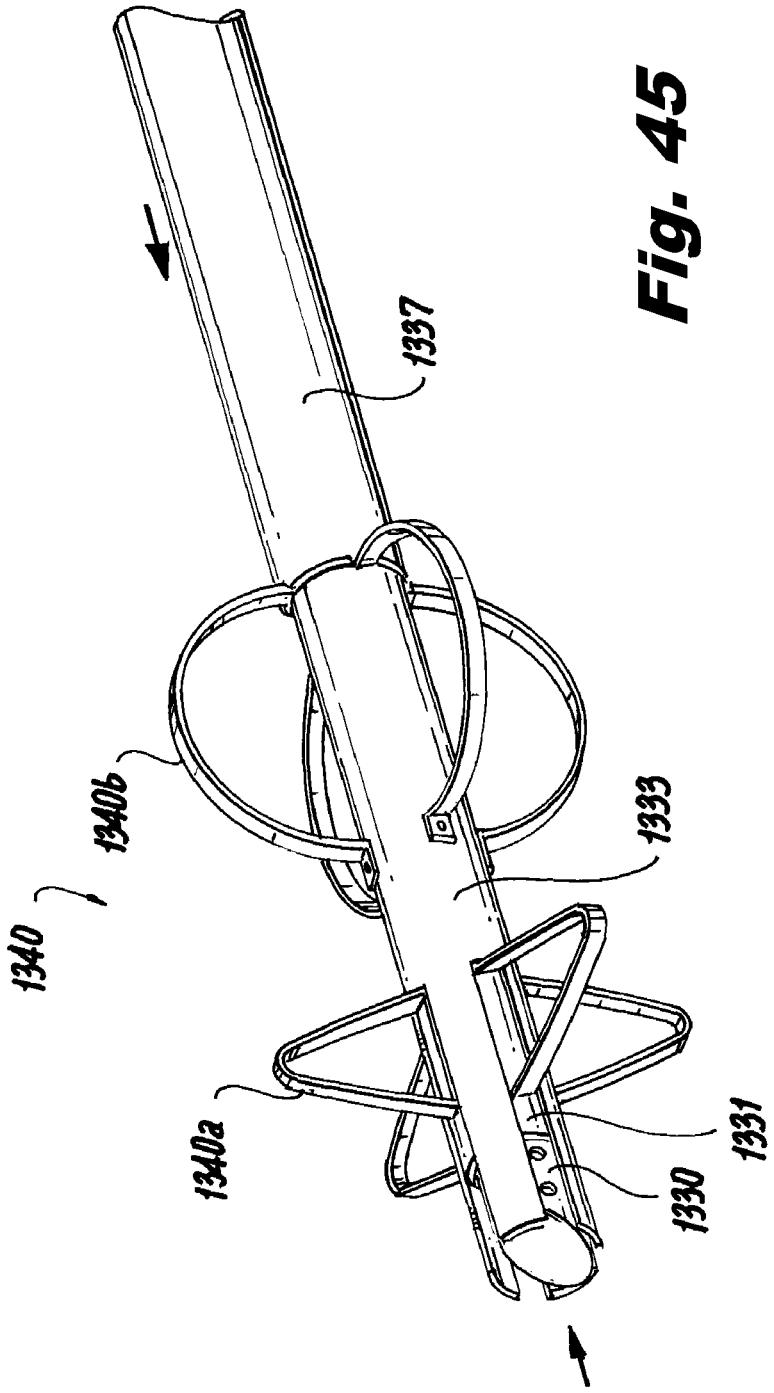

Fig. 45

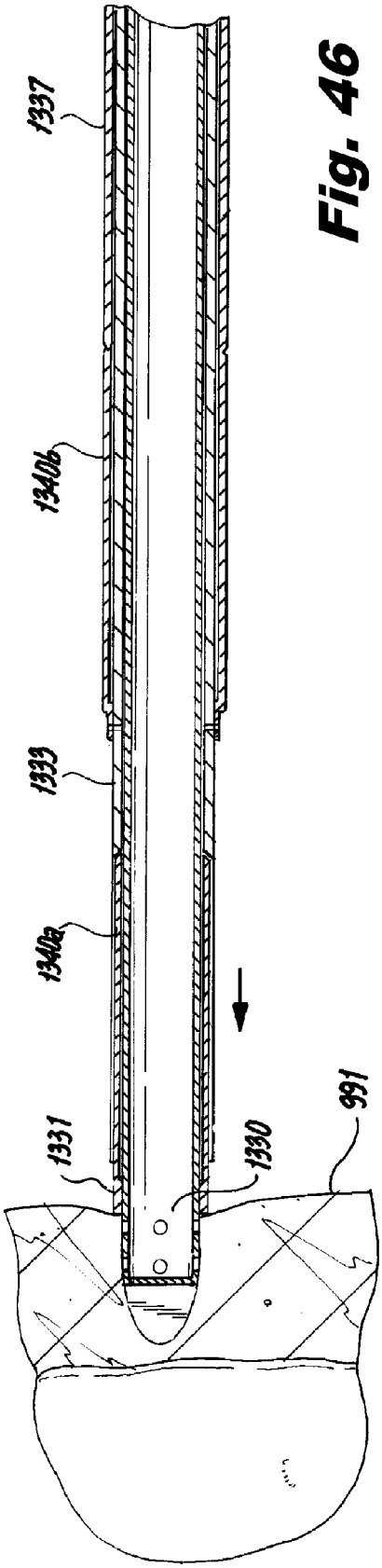

Fig. 46

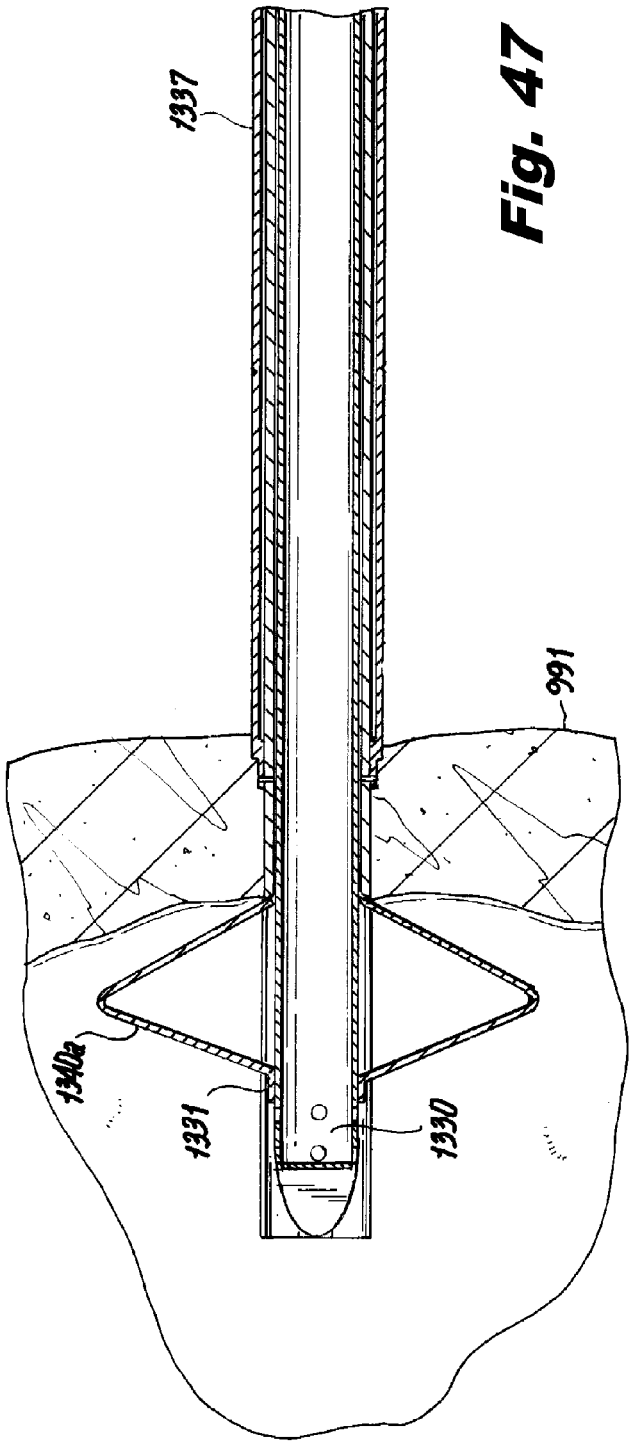

Fig. 47

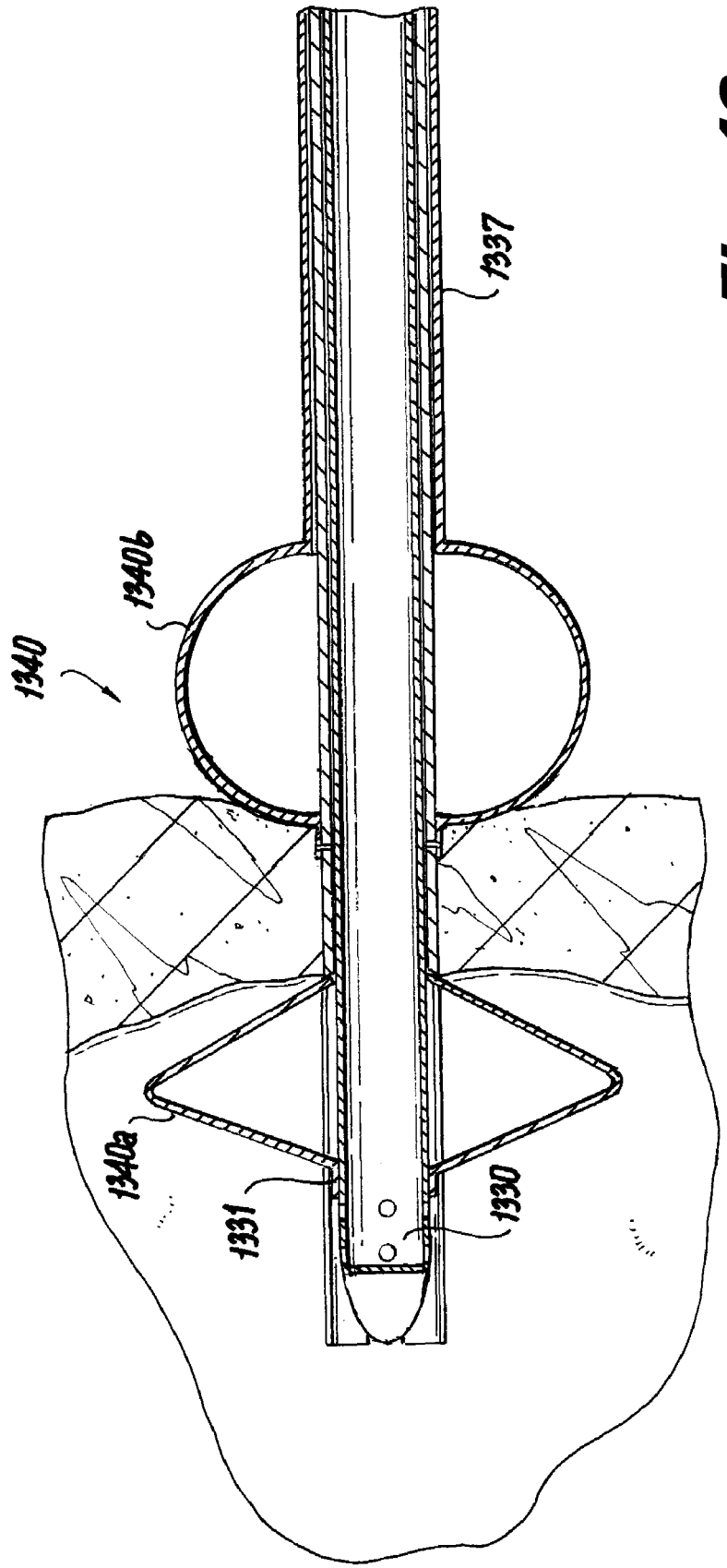

Fig. 48

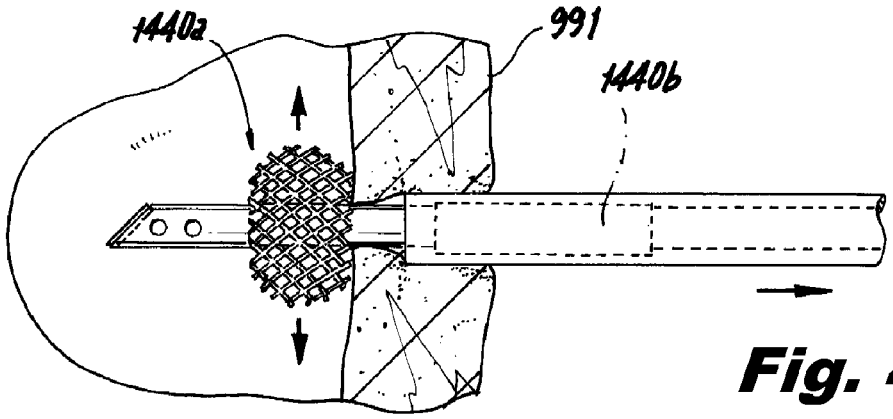

Fig. 49

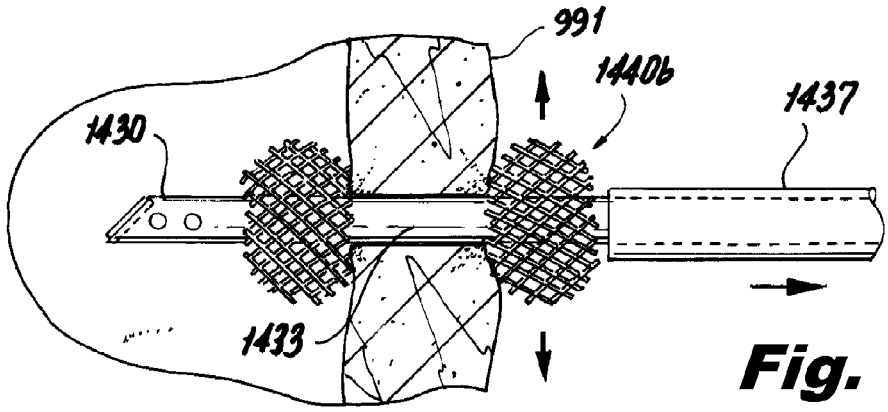

Fig. 50

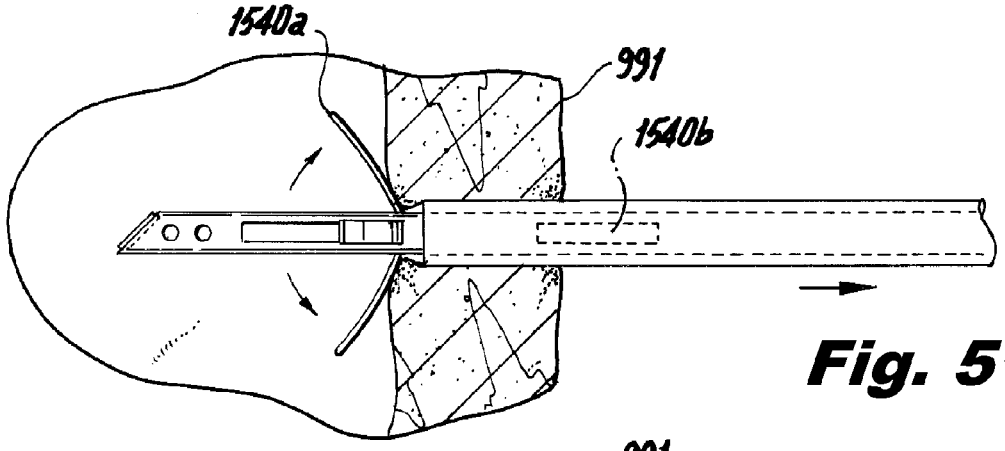

Fig. 51

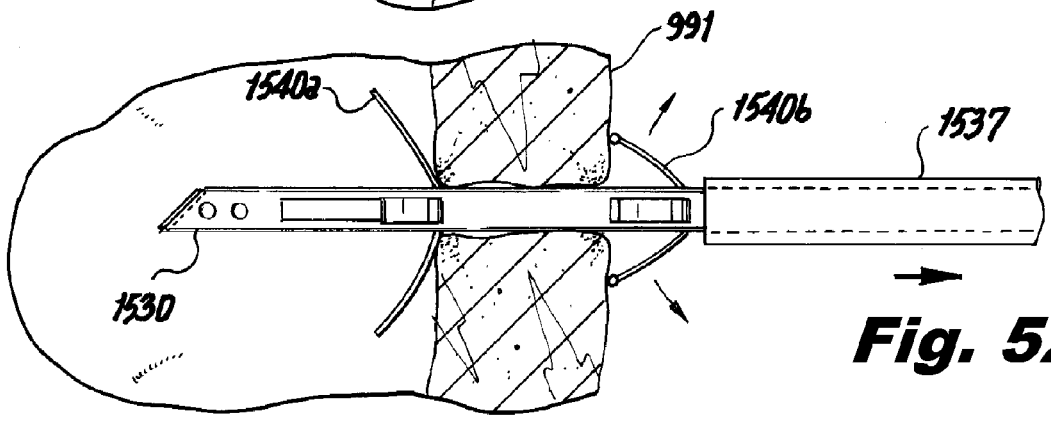

Fig. 52

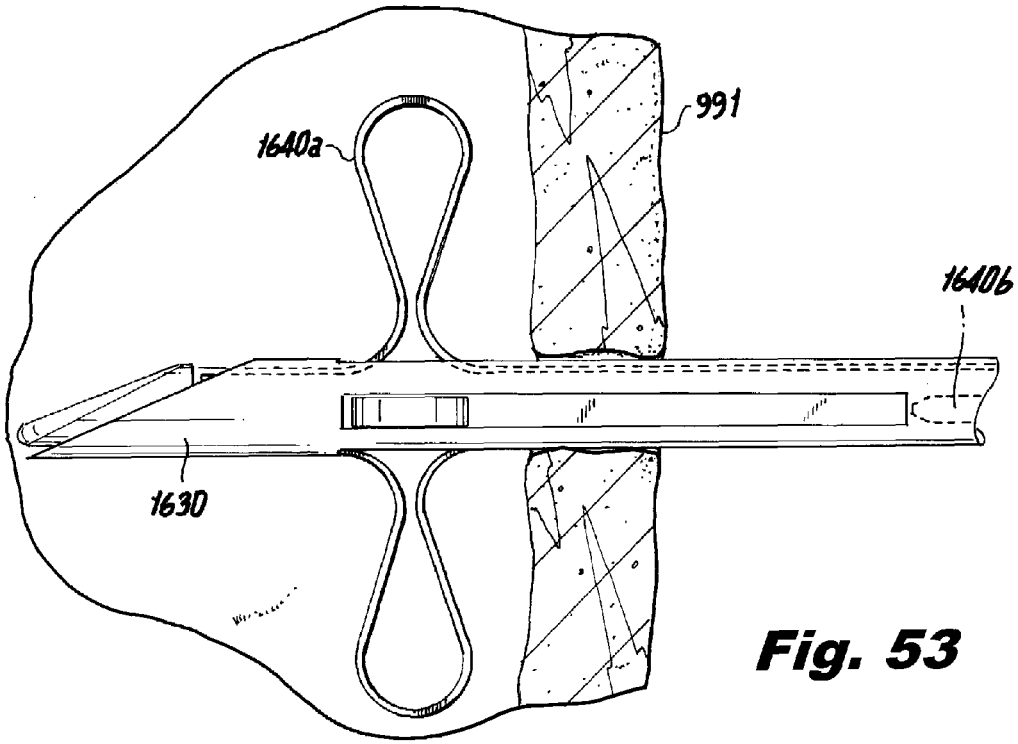

Fig. 53

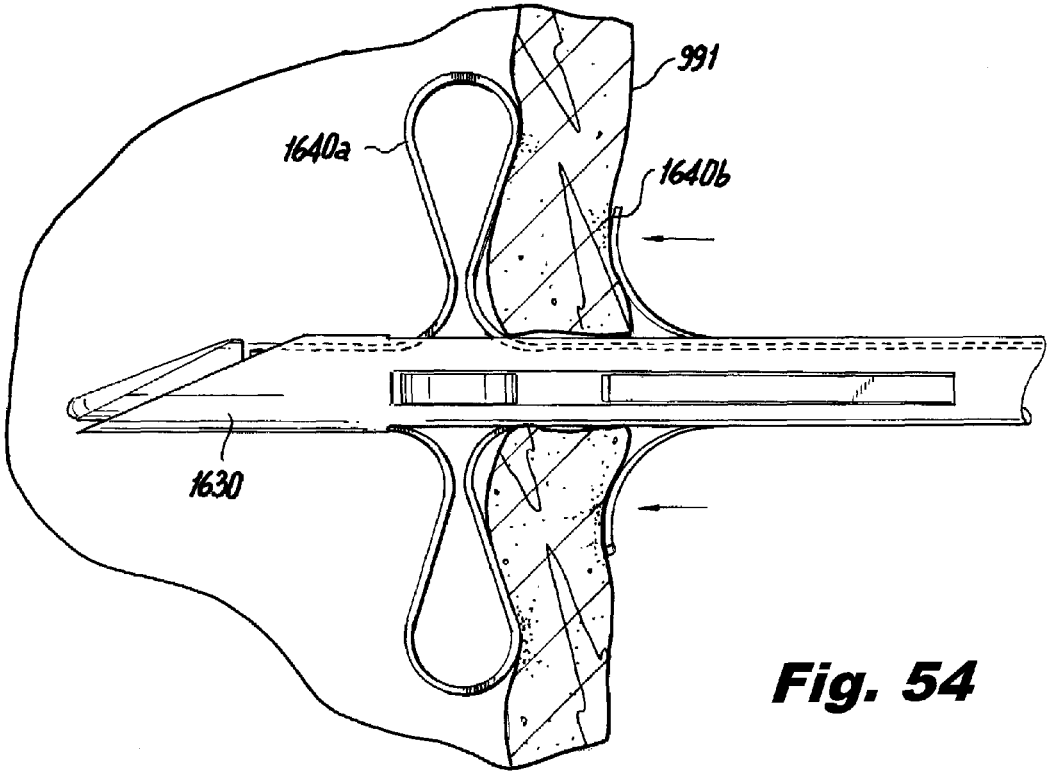

Fig. 54

SURGICAL INSTRUMENTS FOR LAPAROSCOPIC ASPIRATION AND RETRACTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Patent Application Ser. No. 61/291,842, filed Dec. 31, 2009 and U.S. Patent Application Ser. No. 61/323,359, filed Apr. 13, 2010, which are incorporated herein by reference, in their entireties.

FIELD OF THE INVENTION

The present invention relates to surgical procedures. Particularly, the present invention is directed to devices for laparoscopic surgical procedures, and more particularly to devices for use in single-incision laparoscopic surgical (SILS) procedures. The subject surgical devices are deployed, in accordance with one aspect, from within the lumen of a needle or from an outer surface of a needle. Such devices are sometimes termed "needlescopic." U.S. Patent Publications Numbers US 2010/0016884, US 2009/0259225, US 2008/0086166, US 2007/0282170, US 2007/0250112, US 2007/0213767, US 2007/0213766, and US 2007/0213595, each of which is incorporated herein by reference, in its entirety, describe devices related to the devices described herein. The devices described therein, and aspects thereof, including configuration of control mechanisms, material selection, fabrication techniques, as well as other aspects, can be applied to the devices described herein, with advantageous effect.

DESCRIPTION OF RELATED ART

Gallbladder surgery has been revolutionized in recent years, changing from an open incisional surgery to, currently, almost a purely laparoscopic procedure, also known as a minimally invasive surgery. Conventional minimally invasive surgeries for cholecystectomy involve the use of four trocars (access devices). In general, one trocar is inserted in the umbilicus, through which an endoscope is inserted, with two trocars being inserted on the right side of the abdomen for retraction and mobilizing the gallbladder, in order to identify the important structures. The fourth trocar is typically inserted in the midline above the umbilicus.

The aforementioned method has become the standard approach and has withstood twenty years of changes in surgical skill sets, in various groups of surgeons. Relatively recently, even newer and advantageous techniques for cholecystectomy have been developed that involve only a single trocar or "port", called SILS (single incision laparoscopic surgery). The prediction is that nearly twenty to forty percent of all gallbladder surgeries will be performed in this manner in the next five to ten years. This technology involves inserting a single port inserted through the umbilicus, with all the instruments going into the abdominal cavity through the single port. Mobilizing and retracting the gallbladder is challenging with this technology, especially if the gallbladder is distended due to inflammation.

There are techniques available at present for anchoring the fundus of the gallbladder with sutures during SILS procedures, although such techniques are very cumbersome and difficult, especially with an inflamed gallbladder.

Applicants recognize that aspirated, emptied gallbladders are preferable if using SILS technology for cholecystectomy, thus changing what was a tense, full sac, into a malleable

structure permitting instruments to grasp the wall of the gallbladder. Applicants further recognize that simply aspirating with a needle alone, and not sealing the opening caused thereby, will cause spillage of left-over materials, which is not desirable.

Accordingly, there remains a need in the art for devices that facilitate aspiration and retraction of gallbladder in laparoscopic procedures that prevent spillage of gallbladder contents. The present invention provides a solution for these needs.

SUMMARY

In one aspect, a surgical instrument for laparoscopic procedures is provided, which is adapted and configured to aspirate and retract a hollow organ. The surgical instrument includes a needle body, an anchor, deployable with respect to the needle body, adapted and configured for engaging and retracting the hollow organ, and an aperture provided in connection with the needle body, adapted and configured for permitting aspiration of contents of the hollow organ.

The hollow organ can be a gallbladder. The anchor can be held within, and deployable from, a lumen of the needle body. The anchor can be held on, and deployable from, an outside surface of the needle body.

The anchor can be a deployable cage structure. The cage structure can be spring-biased such that the cage structure is deployed by tension provided in a spring when the cage structure extends beyond the needle body by a predetermined distance. The cage structure can include one or more barbs configured to extend from the cage structure when the cage structure is in a deployed configuration. Such one or more barbs can be distally directed to facilitate reinsertion of the cage structure into the lumen of the needle body. Alternatively, such one or more barbs can be proximally directed to facilitate engagement of the barbs with the inner wall of the hollow organ. The cage can be configured so that the barbs move into a position coplanar with surrounding portions of the cage, to facilitate reinsertion of the cage into the lumen of the needle body.

The cage structure can be provided with at least one fenestration to facilitate bending manipulation of the cage.

The cage structure can be provided with a plurality of legs, symmetrically arranged about a longitudinal axis of the surgical instrument. The number of legs can be any or two, three, four, five, six, seven, eight or nine, for example. However, greater or fewer legs, such as one or ten and so on, can be provided.

The cage structure can include a plurality of nested cages to permit flexibility of the cage while maintaining strength sufficient to reliably retract the hollow organ.

In accordance with another aspect of the invention, the anchor can be a deployable wire structure.

Alternatively, the anchor an inflatable structure. The anchor can be adapted and configured to be inflatable by one or more of a liquid and a gas.

The anchor can include a distal anchor portion and a proximal anchor portion, adapted and configured to engage inner and outer surfaces of the hollow organ, respectively. The distal anchor portion and the proximal anchor portion can be longitudinally spaced apart by a distance sufficient to permit engagement of a wall of the hollow organ. If desired, the distal anchor portion and the proximal anchor portion can be rotationally offset from one another by about 90 degrees, with respect to a longitudinal axis of the surgical instrument. Alternatively, the distal anchor portion and the proximal anchor

portion can be substantially parallel with one another, with respect to a longitudinal axis of the surgical instrument.

The distal anchor portion and the proximal anchor portion can be of substantially the same configuration. Alternatively, the distal anchor portion and the proximal anchor portion can be of dissimilar configurations, such as in structure, number of elements, size, material, or in other aspects thereof.

In accordance with the invention, the needle body can include a sharpened distal tip. A deployable tip protector can further be provided to inhibit unintentional injury by a sharpened distal tip of the needle body. The deployable tip protector can be a translatable sheath adapted and configured to be deployed over the sharpened distal tip of the needle body. Alternatively, the deployable tip protector can be a translatable plug adapted and configured to be deployed from within a lumen of the needle body. The plug can be adapted and configured to extend distally beyond the sharpened distal tip of the needle body, to inhibit piercing of a structure by the needle body, when in a deployed position. The plug can be formed from a polymeric material.

In accordance with the invention, an aperture can be provided at the distal end of the body. Alternatively, one or more apertures can be provided in a distal end portion of a sidewall of the body.

The anchor can be formed at least in part from one of a shape-memory alloy and a stainless steel. Alternatively, resilient polymeric materials of sufficient strength, flexibility and durability can be used. In accordance with the invention, the anchor can be formed at least in part by laser cutting.

The needle body can be any length necessary. In accordance with one aspect, the length is about 20 centimeters. An outer diameter of the needle body can be any size necessary. In accordance with one aspect, the diameter is about 2 mm.

The anchor can be configured such that, in a deployed conformation, a width, measured transverse to a longitudinal axis thereof, is a maximum of about eight times that of a width in a collapsed conformation, measured transverse to the longitudinal axis thereof.

The needle body can be provided with a sharpened end surface angled at about 35 degrees with respect to the longitudinal axis of the needle body.

A handle can be provided in connection with the subject instruments, to facilitate manipulation thereof.

In accordance with a further aspect of the invention, a method of retracting a hollow organ is provided, comprising the steps of inserting a body through an abdominal wall of a patient, inserting the body through a wall of the hollow organ, aspirating contents from the hollow organ, deploying a first anchor portion within the hollow organ, to engage an inner surface of the hollow organ, and retracting the hollow organ.

In accordance with the invention, the method can further include the step of deploying a second anchor portion outside the hollow organ to engage an outer surface of the hollow organ.

In accordance with still another aspect of the invention, a surgical instrument for laparoscopic procedures is provided, which is adapted and configured to aspirate and retract a gallbladder, the instrument having means for aspirating contents from a gallbladder, and means for engaging and retracting the gallbladder.

In accordance with still a further aspect of the invention, a surgical instrument can be manufactured by a process comprising the steps of providing a tubular needle with a lumen extending therethrough, machining a deployable anchor, and inserting the deployable anchor, in a radially collapsed conformation, into the tubular needle. The anchor can be formed from a flat stainless steel stock material. The step of machining can be performed by electrical discharge machining or laser machining, for example.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and are not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute part of this specification, are included to illustrate and provide a further understanding of the devices and related methods of the invention. Together with the description, the drawings serve to explain the principles of the invention, wherein:

FIGS. **1-14** show various views of a surgical aspirator-retractor in accordance with the present invention, having a deployable anchor element thereof, in a cage having a rosette configuration;

FIG. **1** is an isometric view of a first representative embodiment of a surgical aspirator-retractor in accordance with the present invention, with a distal anchor portion thereof shown in a collapsed condition;

FIG. **2** is an isometric view of the surgical aspirator-retractor of claim **1**, with a distal anchor portion thereof shown in an expanded condition;

FIG. **3** is a side view of the surgical aspirator-retractor of FIG. **1** in accordance with the present invention, with a distal anchor portion thereof shown in a collapsed condition;

FIG. **4** is a detailed isometric view of the distal anchor portion of the surgical aspirator-retractor of FIG. **1**, shown in a collapsed condition;

FIG. **5** is a detailed isometric view of the distal anchor portion of the surgical aspirator-retractor of FIG. **1**, shown in an expanded condition;

FIG. **6** is a detailed isometric view of the distal anchor portion of the surgical aspirator-retractor similar in all respects to the embodiment of FIG. **1**, but with a solid tip and apertures for aspiration on a side surface thereof, shown in a collapsed condition;

FIG. **7** is a detailed isometric view of the distal anchor portion of the surgical aspirator-retractor of FIG. **6**, shown in an expanded condition;

FIG. **8** is a proximal isometric view of the surgical aspirator-retractor of FIG. **1**;

FIG. **9** is a proximal end view of the surgical aspirator-retractor of FIG. **1**;

FIG. **10** is a distal end view of the surgical aspirator-retractor of FIG. **1**;

FIGS. **11-14** illustrate use of the surgical aspirator-retractor of FIG. **1**, in piercing, aspirating contents of and retracting a gallbladder, respectively;

FIGS. **15-22** show various views of a further embodiment of a surgical aspirator-retractor in accordance with the present invention, having a hook-shaped distal anchor element;

FIG. **15** is a distal isometric view of a further embodiment of a surgical aspirator-retractor in accordance with the invention, shown with a distal anchor portion thereof in a retracted condition;

FIG. **16** is a distal isometric view of the surgical aspirator-retractor of FIG. **15**, shown with a distal anchor portion thereof in a deployed condition;

FIG. **17** is a side view of the surgical aspirator-retractor of FIG. **15**, shown with a distal anchor portion thereof in a deployed condition;

FIG. **18** is a detail isometric view of a distal anchor portion of the surgical aspirator-retractor of FIG. **15**;

FIGS. **19-22** illustrate use of the surgical aspirator-retractor of FIG. **15**, in piercing, aspirating contents of and retracting a gallbladder, respectively;

FIGS. **23-31** show various views an additional embodiment of a surgical aspirator-retractor in accordance with the present invention, having a deployable cage anchor;

FIG. **23** is an isometric view of a surgical aspirator-retractor, having a deployable cage stowed within a lumen of a needle body;

FIG. **24** is a detail isometric view illustrating the deployable cage of the surgical aspirator-retractor of FIG. **23**, stowed within the lumen of a needle body;

FIG. **25** is a detail isometric view illustrating the deployable cage of the surgical aspirator-retractor of FIG. **23**, partially deployed from the lumen of the needle body;

FIG. **26** is a detail isometric view illustrating the deployable cage of the surgical aspirator-retractor of FIG. **23**, fully deployed from the lumen of the needle body;

FIG. **27** is a detail cross-sectional view illustrating an example deployment mechanism for the cage of the surgical aspirator-retractor of FIG. **23**;

FIG. **28** is a detail isometric view illustrating a barb provided on the deployable cage of the surgical aspirator-retractor of FIG. **23**;

FIG. **29** is a detail isometric view illustrating a distal end portion of the deployable cage of the surgical aspirator-retractor of FIG. **23**;

FIG. **30** is an isometric view of a distal anchor portion of a surgical aspirator-retractor in a deployable cage configuration, which is similar in many respects to the embodiment of FIG. **23**, but with a plurality of nested layers and additional fenestrations to facilitate a change in conformation thereof;

FIG. **31** is a detail isometric view of the distal anchor portion of the surgical aspirator-retractor of FIG. **30**;

FIGS. **32-34** show various views of still another embodiment of a surgical aspirator-retractor in accordance with the present invention having a deployable cage formed by outwardly expanding ribbons of material;

FIG. **32** is a distal isometric detail view of a surgical aspirator-retractor, with a needle tip portion covered by a sheath to inhibit unintentional damage to an anatomical structure;

FIG. **33** is a distal isometric detail view of the surgical aspirator-retractor of FIG. **32**, with a needle tip portion exposed by the sheath;

FIG. **34** is a distal isometric detail view of the surgical aspirator-retractor of FIG. **32**, shown in an expanded conformation;

FIGS. **35-36** show various views of a further embodiment of a surgical aspirator-retractor in accordance with the present invention having distal deployable anchor as a deployable cage, formed by axially offset pairs of outwardly expanding anchor portions formed of ribbons of material, for engaging inner and outer wall surfaces, respectively, of a hollow organ;

FIG. **35** is an isometric view of the surgical aspirator-retractor, showing the anchor portions in a deployed conformation;

FIG. **36** is an exploded view of the surgical aspirator-retractor;

FIG. **37** is an isometric view of a distal end portion of a further embodiment of a surgical aspirator-retractor in accordance with the invention having deployable ribbon elements with barbs formed thereon to facilitate engagement with a hollow structure;

FIG. **38** is an isometric view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention having deployable ribbon elements for deploying respective elongated barbs;

FIG. **39** is an isometric view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention, having an axial, radially deployable wire anchor;

FIG. **40** is an isometric view of a distal end portion of another embodiment of a surgical aspirator-retractor in accordance with the invention, having a helical, radially deployable wire anchor;

FIG. **41** is an isometric view of a distal end portion of another embodiment of a surgical aspirator-retractor in accordance with the invention, having a single inflatable distal anchor element;

FIG. **42** is an isometric view of a distal end portion of a further embodiment of a surgical aspirator-retractor in accordance with the invention, having a plurality of inflatable distal anchor elements, for respectively engaging inner and outer surfaces of a hollow organ, such as a the gallbladder;

FIGS. **43-48** show various views of still a further embodiment of a surgical aspirator-retractor in accordance with the present invention having axially offset pairs of outwardly expanding anchor portions formed of ribbons of material, for engaging inner and outer wall surfaces of a hollow organ, respectively;

FIG. **43** is an isometric view of a distal end portion of the surgical aspirator-retractor in accordance with the invention, shown with the anchor portion in a collapsed configuration;

FIG. **44** is an exploded view of the surgical aspirator-retractor of FIG. **43**;

FIG. **45** is an isometric view of a distal end portion of the surgical aspirator-retractor of FIG. **43**, shown with the anchor portion in a deployed configuration;

FIG. **46-48** are side views illustrating insertion and deployment of the of the surgical aspirator-retractor of FIG. **43** within and outside of a hollow organ, and subsequent engagement thereof;

FIG. **49** is a side view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention, having two expandable mesh distal anchor elements, with the distalmost anchor deployed;

FIG. **50** is a side view of a distal end portion of the surgical aspirator—of FIG. **49**, having a pair of expandable mesh distal anchor elements, with both anchor elements deployed;

FIG. **51** is a side view of a distal end portion of a surgical aspirator-retractor having distal and proximal prong-shaped engagement elements, with only inner anchor elements deployed;

FIG. **52** is a side view of a distal end portion of the surgical aspirator-retractor of FIG. **51** with both inner and outer anchor elements deployed;

FIG. **53** is a side view of a distal end portion of an additional embodiment of a surgical aspirator-retractor in accordance with the invention, having distal deployable ribbon-shaped engagement elements; and

FIG. **54** is a side view of a distal end portion of the surgical aspirator-retractor of FIG. **53**, having distal deployable ribbon-shaped engagement elements and proximal deployable prong-shaped engagement elements, with all elements in a deployed configuration.

DETAILED DESCRIPTION

Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings.

In accordance with one aspect of the invention, a surgical aspirator-retractor is provided having the capacity to aspirate and seal a hole formed thereby, as well as retract the gallblad-

der. In accordance with one aspect, a needle of less than 2.5 mm is introduced into the abdominal wall with a sharp tip which can pierce the skin. The same needle tip is able to pierce the fluid-filled gallbladder wall. The opposite end to the needle tip can be provided with a hub to attach a syringe or suction device to help to aspirate the contents of the gallbladder. Once the gallbladder is emptied of its contents, the surgical aspirator-retractor's anchor or fixation mechanism can be deployed.

In accordance with the invention, the distal anchor or fixation mechanism can include, for example, multiple curved wires coming out of the sharp end of the needle, multiple curved wires coming out of the shaft near the needle tip, an outer shaft over the needle having a shape-memory alloy wire attached to two ends and when pushed down, the wire assumes the shape of a rosette. Depending on the precise implementation, the needle tip can be split at the end and when retracted backwards can become the shape of a star. If desired, a separate instrument can be provided having a compressed hook, introduced at the proximal end of a needle body. When the separate instrument is inserted through and beyond a distal end of the needle body, it is deployed, and the hook engages the inside of the gallbladder wall.

Depending on the precise embodiment, once this distal anchor portion is deployed, the whole instrument is withdrawn until the sharp tip of the anchor engages and fixes to the inside of the gallbladder wall firmly. Optionally, a second anchor portion can be provided to engage the outer surface of the wall of the gallbladder to facilitate a secure grasp. The gallbladder can then be retracted or mobilized in any direction without any spillage. Once the gallbladder dissection from the liver is complete, the anchor mechanism is either retracted into the instrument or otherwise straightened, thus releasing its attachment from the gallbladder wall. The instrument will then be withdrawn from the gallbladder wall.

It should be noted that although the devices of the present invention are advantageous for cholecystectomy procedures, they can advantageously be applied to aspirate, retract and/or stabilize other hollow organs, such as the stomach or urinary bladder, for example. Further, devices in accordance with the invention can be used to manipulate other tissues including organs, in addition to those that are substantially hollow.

Devices in accordance with the invention advantageously help empty the contents from the organ with which it is being used, such as the gallbladder, without spillage, and facilitate easy grasping of the wall of the thereof because of loss of distensability of the organ wall is reduced. The subject devices also permit easy removal of the gallbladder from the abdominal cavity through the umbilical port due to the collapsed state of the organ. Further, advantageously, the small size of the subject instruments minimize or eliminate scarring.

For the purposes of explanation and illustration, and not limitation, in accordance with the invention, an exemplary embodiment of a surgical aspirator-retractor **100** is illustrated in FIGS. **1-14**. In accordance with this example, the surgical aspirator-retractor includes an inner needle having a diameter, for example 1.5 mm, and a needle body **130** having diameter d**1**, for example about 2 mm, with a length L**1**, for example about 200 mm.

As illustrated in FIGS. **11-14**, which illustrate use of the surgical aspirator-retractor of FIG. **1**, in piercing, aspirating contents of and retracting a gallbladder, respectively, the aspirator-retractor **100** can be positioned directly over the gallbladder **991** then inserted directly through the skin of the abdominal wall **990**, into the gallbladder **991**, by virtue of a sharpened distal tip **131**. A suction source can be hooked up to a fitting **115**, such as a Luer fitting provided on the body **110**, and the gallbladder is aspirated of its contents **993**, such as bile, from the lumen **995** thereof, via a distal end aspiration aperture **135** therein. The thumb wheel **120** can then be advanced to deploy the anchor **140**, which in the illustrated embodiment is in the form of a cage with hooks or barbs **141** to engage or imbed into the gallbladder **991**, for retention thereof. The surgical aspirator-retractor **100** is then pulled up setting the tips of the cage into the gallbladder internally. The surgical aspirator-retractor **100** can then be pulled up and the gallbladder is raised to the desired position. The position locking mechanism **150** is placed against the skin and locked, thereby suspending the gallbladder in the body cavity allowing work to be performed on it and around it without having to reposition the gallbladder continually.

As best seen in the detail views of FIGS. **4** and **5**, an outer shaft **133** is provided concentrically outside of the needle body **130**, and is attached to the proximal end of the anchor **140**, while the distal end of the anchor **140** is attached to the needle body. Such attachment can be achieved by integral forming process, welding, crimping, mechanical fasteners, adhesives or another suitable technique, if desired.

FIGS. **6** and **7** are is an isometric detail views of the distal anchor portion **140** of the surgical aspirator-retractor **100**, but with a solid tip **132** and apertures **137** for aspiration on a side surface thereof, shown in a collapsed condition and a deployed condition, respectively.

In accordance with a further exemplary embodiment, as illustrated for example, in FIGS. **15-22**, a surgical aspirator-retractor **200** is provided with a needle body **230**, a distal anchor **240**, a handle **210**, a proximal fitting **215** and a position locking mechanism **150**. The needle body **230** can have, in accordance with one example embodiment, a diameter of about 1.5 mm and a length of between about 150 mm and 200 mm.

As best seen in FIGS. **19-22**, which illustrate use of the surgical aspirator-retractor of FIG. **15**, in piercing, aspirating contents of and retracting a gallbladder, respectively, as with the above-described embodiment, the aspirator-retractor **200** can be positioned over the gallbladder **991**, and then inserted directly through the abdominal wall **990**, into the lumen **995** of the gallbladder **991**. Suction can then be hooked up to the luer fitting **215** on the end thereof, and the gallbladder **991** is aspirated of its contents **993**, such as bile. Suction can then be turned off and the anchor **240** advanced, as shown in FIG. **21**, to expose a single or multiple needle tips (e.g., similar to a grappling hook). As shown in FIG. **22**, the surgical aspirator-retractor **200** is then pulled up setting the needles into the inner surface of the wall of the gallbladder **991**. Then, the surgical aspirator-retractor **200** is pulled up and the gallbladder is raised to the desired position. The position locking mechanism **150** is placed against the skin and locked, thereby suspending the gallbladder in the body cavity allowing work to be preformed on it and around it without having to continually reposition the gallbladder **991**.

FIGS. **23-31** show various views an additional embodiment of a surgical aspirator-retractor in accordance with the present invention, having a deployable cage-shaped anchor **340**.

By way of example, the needle body **130** is provided as a hollow needle. In accordance with one aspect, the diameter of the needle body **130** can be about 2.1 mm. In use, the needle body is inserted through the abdomen under internal observation. The needle body **130** is inserted into the gallbladder **991** and fluids are aspirated through the needle body **130**. A shaft **340**, which may be formed from a tubular material, and being internal to the needle body **130**, is advanced distally to

deploy the expandable cage-shaped anchor **340**, which is affixed to the front of the tube **338**. A shaft **343** runs through a lumen of the tube **338**, and is attached to the distal portion of the anchor cage **340**. As best seen in FIG. **27**, a spring **345** is provided and is secured to the shaft **343**, thus spring loading the anchor cage **340**, under tension applied thereto. When the anchor cage **340** is advanced beyond the needle body **130**, the tension of the spring **345** causes the cage to expand up to a stop. Bending of the anchor cage **340** exposes grip fingers or barbs **341** that secure the inside of the gall bladder **991**.

In use, the internal components are typically recessed inside the 2.1 mm hollow needle body **130**. The needle body **130** is then inserted through the abdomen and then into the gallbladder **991**. Fenestrations **349** facilitate achieving the desired structural properties of the anchor cage **340**, and also permit fluids to be aspirated past the distal tip of the anchor cage **340**. Once the gallbladder **991** is aspirated, the anchor cage **340** is advanced through the needle body **130**, and into the lumen **995** of the gallbladder **991**. In accordance with one aspect, the anchor cage **340** expands outwardly, to a maximum width of about 16 mm. In the illustrated embodiment, the barbs **341** face distally, so that there are no edges to catch on the needle body **130**, when the cage **340** is drawn back into the needle body **130**.

After insertion within the lumen **995** of the gallbladder **991** and deployment of the anchor **340**, the aspirator-retractor can be manipulated such as by rotation or axial translation, to facilitate access to the gallbladder **991**. Once removed, the gallbladder **991** is placed in a bag, for example, and the anchor cage **340** is retracted to release the gallbladder **991** from the aspirator-retractor, which is then removed from the patient.

To retract the anchor cage **340**, the inner drive tube **338** is retracted. The gallbladder is then stripped from the aspirator-retractor. The anchor cage **340** is then returned to its original position and the needle body **130** is removed from the abdomen.

In accordance with the invention, the anchor cage **340** is assembled by any suitable technique, to the inner tube **338**, such as by welding, soldering or crimping. In accordance with the invention, the shaft **343** can be connected to the anchor cage **340** by a threaded connection, or other suitable technique.

Due to the high amount of flex and associated strain placed on the cage, material must be selected accordingly. Shape memory alloys or any suitable materials can be used. In accordance with one aspect, a high strength stainless steel alloy is used in cased of thin cross-sections, to maintain stresses below their tensile limits. In accordance with the invention, 17-7PH Condition C stainless steel with a post forming heat-treatment to condition CH900 can be utilized for this application. In accordance with the invention, such a material can have a tensile strength of approximately 250,000 psi and elongation of 3% expected, with minimal part distortion during heat-treatment. If desired, a flash electropolish and subsequent low temperature bake to prevent Hydrogen embrittlement can be used to remove heat tint during 900 degree F. open air precipitation age hardening.

FIG. **30** is an isometric view of a distal anchor **340** of a surgical aspirator-retractor having a deployable cage configuration, which is similar in many respects to the embodiment illustrated in FIG. **23**. The anchor cage **440** differs therefrom in that it includes a plurality of nested layers **440***a*, **440***b*, and additional fenestrations **449**, to promote strength while facilitate a reliable change in conformation thereof in use. FIG. **31** is a detail isometric view of the distal anchor portion **440** of the surgical aspirator-retractor of FIG. **30**. In accordance with one aspect of the invention, the anchor cage **340** and/or the anchor cage portions **440***a*, **440***b* can be formed from a stainless steel material having about a 0.002 inch stock thickness.

With reference to FIGS. **32-34**, still another embodiment of a surgical aspirator-retractor in accordance with the present invention is illustrated, having a distal anchor **540** in a variation of the above-described deployable cage structures. The distal anchor **540** includes outwardly expanding ribbons of material **540***a*, **540***b*. A main needle body **530** is provided, axially inner to other components. A deployable tip protector **537** is also provided. As illustrated in FIG. **32**, the tip protector **537** is here illustrated as a sheath which can be deployed by manipulating respective concentric tube(s), such as one provided radially outward from the main needle body **530**. As best seen in FIG. **34**, when a compressive force is applied distally on the ribbons **540***a*, **540***b*, they expand radially outwardly, as with other embodiments described herein, due to the configuration thereof and material selection therefor.

FIGS. **35-36** illustrate a further embodiment of a surgical aspirator-retractor in accordance with the present invention having a distal deployable anchor **640** as a deployable cage, formed by axially offset pairs of outwardly expanding anchor portions **640***a*, **640***b*, which are generally ribbon-shaped in configuration.

In accordance with the invention, the needle body **630** can be configured as desired. In accordance with one aspect of the invention, the needle body **630** has about a 2.1 mm outer diameter and 225 mm length. A safety plug **639** can be provided for the same reason as the sheath **537** of the above-described embodiment, namely to inhibit unintentional trauma to the patient when the needle body **130** is not intentionally and actively being inserted through anatomy. In the safe position illustrated in FIG. **35**, a sharp tip of the needle body **630** is shielded by the plug **639**, which extends distally past the tip thereof.

Conversely, to pierce a structure, the plug **639** is retracted by withdrawing the cage **640** proximally. Suction applied to a central lumen allows for aspiration of contents through the lumen, around the plug **639**. Alternatively or additionally, fluid can be aspirated through the (four) fenestrations in the needle body **630** provided for the expanding anchor portions **640***a*, **640***b*. Aspirated contents can be carried through an inner tube and to the connected suction system.

Later, for deployment of the anchor portions **640***a*, **640***b*, the cage **640** is urged distally, which also results in the plug **639** being placed in the safety position. In the illustrated embodiment, tabs formed by on respective legs of the cage **640** engage respective slots in a pushing element, or expander **642** and a pusher tip **644**. The expander **642** and pusher tip **644** can be welded to respective inner and outer tubes, such as actuator **646**, that can be move axially relative to one another, to enable control of deployment of the cage **640**.

In use, an inner tube (not illustrated) connected to the expander **642**, can be advanced distally to deploy the distal grasper portions **640***b*, within the gallbladder. The whole aspirator-retractor can then be retracted proximally until the set of distal anchor portions **640***b* are engaged with an inner surface of the gallbladder wall. The outer tube **646**, connected to the pusher **644** can then be advanced to open the proximal grasper portions **640***a*, to expand on the outside of the gallbladder, sandwiching the wall of the gallbladder therebetween.

Thus, the aspirated gallbladder is securely held by the aspirator-retractor and is able to be manipulated by the surgeon while it is dissected from connecting vessels and tissues. In accordance with one aspect, the gallbladder can then be placed in an endoscopic collection bag and both inner and

outer tubes can be retracted to pull the anchor portions **640***a*, **640***b* inside of the needle body **630**, to release the gallbladder. Subsequently, the aspirator-retractor can then be removed from the abdomen and discarded.

As with other embodiments set forth herein, the illustrated configuration of an aspirator-retractor can be integrated with handles described herein.

As with other embodiments described herein, the anchor portions **640***a*, **640***b* extend through respective apertures, which are formed, in this case, in the needle body **630** by a suitable technique, such as by laser cutting.

In accordance with one aspect, the anchor cage portions **640***a*, **640***b* can be formed of a 0.005 inch-thick, full hard stainless steel, or another suitable material. The Anchor cage **640** can be formed from a single or a plurality of nested layers.

Various additional alternative embodiments of aspirator-retractors in accordance with the invention are provided, as follows.

FIG. **37** is an isometric view of a distal end portion of a further embodiment of a surgical aspirator-retractor **700** in accordance with the invention having deployable ribbon elements **740***a*, **740***b* with barbs formed thereon to facilitate engagement with a hollow structure. Construction and operation of the aspirator-retractor **700** is in keeping with other embodiments described herein, such as with the embodiment of FIGS. **35** and **36**.

FIG. **38** is an isometric view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention having a distal anchor element **840** formed by deployable ribbon elements **840***a* for deploying respective elongated barbs **840***b*.

FIG. **39** is an isometric view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention, having an axial, radially deployable wire anchor **940**, deployable from the needle body **930** thereof. Deployment of the anchor **940** can be effected by providing distally-directed force to an actuating rod, connected to a proximal end of the wire anchor **940**, and concentrically disposed within the lumen of the needle body **930**.

FIG. **40** is an isometric view of a distal end portion of another embodiment of a surgical aspirator-retractor in accordance with the invention, having a helical, radially deployable wire anchor **1040**. A distal portion of the helical wire anchor **1040** is secured to a main needle body **1030**, while a proximal end portion of the helical wire anchor **1040** is secured to a concentrically outer actuating tube **1033**. Therefore, relative movement between the main needle body **1030** and the outer tube **1033**, including rotation and/or translation, can effect deployment of the anchor **1040**. The distal end **1032** can be solid, or open, or can include apertures for aspiration on side surfaces thereof.

FIG. **41** is an isometric view of a distal end portion of another embodiment of a surgical aspirator-retractor in accordance with the invention, having a single inflatable distal anchor element **1140** carried by a needle body **1130**. The inflatable distal anchor element **1140** can be inflated via one or more channels formed within the needle body **1130**, and configured and adapted to be insufflated by a liquid, such as saline, or a gas, such as compressed air or carbon dioxide. As with any of the embodiments described herein, the distal end **1032** can be solid, or open, or can include apertures for aspiration on side surfaces thereof.

FIG. **42** is an isometric view of a distal end portion of a further embodiment of a surgical aspirator-retractor in accordance with the invention, having a plurality of inflatable distal anchor elements **1240***a*, **1240***b*, provided on a needle body **1230**, for respectively engaging inner and outer surfaces of a hollow organ, such as a the gallbladder. The inflatable anchor elements **1240** can be inflated via one or more channels formed within the needle body **1230**, and configured and adapted to be insufflated by a liquid, such as saline, or a gas, such as compressed air or carbon dioxide. As with any of the embodiments described herein, the distal end **1032** can be solid, or open, or can include apertures for aspiration on side surfaces thereof.

FIGS. **43-48** illustrate various views of still a further embodiment of a surgical aspirator-retractor in accordance with the present invention having a distal anchor **1340** with axially offset pairs of outwardly expanding anchor portions **1340***a*, **1340***b*, formed of ribbons of material, for engaging inner and outer wall surfaces of a hollow organ, respectively, as described above in connection with other embodiments. In accordance with this embodiment, a moveable inner shaft **1331** is provided over the needle body **1330**, over which a stationary intermediate shaft **1333** is provided, over which a moveable outer shaft **1337** is provided. Each of the moveable shafts is controllable, with respect to the stationary main needle body **1330** and intermediate shaft **1333**. In accordance with the invention, distally-directed compressive forces result in radial outward expansion of the respective anchor portions **1340***a*, **1340***b*. As with any of the embodiments described herein, apertures **1337** for aspiration can be provided on side surfaces of the needle body **1330**.

FIG. **49** is a side view of a distal end portion **1440***a* of still a further embodiment of a surgical aspirator-retractor in accordance with the invention, having an expandable mesh distal anchor elements.

FIG. **49** is a side view of a distal end portion of still a further embodiment of a surgical aspirator-retractor in accordance with the invention, having two expandable mesh distal anchor elements **1440***a*, **1440***b*, with the distalmost anchor **1440***a* in a deployed, expanded conformation. FIG. **50** is a side view of the surgical aspirator of FIG. **49**, with both anchor elements deployed, sandwiching a wall of the gallbladder therebetween. As with other embodiments, the mesh distal anchor elements **1440***a*, **1440***b* are connected to coaxial elements to permit manipulation thereof.

FIG. **51** is a side view of a distal end portion of the surgical aspirator-retractor having proximal and distal prong-shaped anchor elements **1540***a*, **1540***b*, with only distal anchor elements **1540***a* deployed. FIG. **52** is a side view of the surgical aspirator-retractor of FIG. **51** with both inner (distal) **1540***a* and outer (proximal) **1540***b* anchor elements deployed. An outer sheath **1537** is provided to facilitate stowing of the anchor elements when retraction is completed.

FIG. **53** is a side view of a distal end portion of an additional embodiment of a surgical aspirator-retractor in accordance with the invention, having distal deployable ribbon-shaped engagement elements **1640***a*, and proximal deployable prong-shaped engagement elements **1640***b*, adapted and configured for deployable from common slots provided in the needle body **1630**. FIG. **54** is a side view illustrating all anchor elements in a deployed configuration, thereby sandwiching the wall of the gallbladder **991** therebetween.

It will be apparent to those skilled in the art that various modifications and variations can be made in the device and method of the present invention without departing from the spirit or scope of the invention. It is particularly conceived that elements of one embodiment described herein can advantageously be applied to any embodiment of devices in accordance with the invention, even if such features are not explicitly described in connection therewith, unless such feature should be mutually exclusive or otherwise incompatible with other features of such embodiment. Thus, it is intended that

the present invention include modifications and variations that are within the scope of the appended claims and their equivalents.

What is claimed is:

1. A surgical instrument for laparoscopic procedures, adapted and configured to aspirate and retract a hollow organ, comprising:

a needle body defining an aperture adapted and configured for aspirating contents of the hollow organ, the needle body including a sharpened distal tip;

an outer shaft operatively disposed radially outward of the needle body and longitudinally translatable relative thereto; and

an anchor, having a proximal end mounted to the outer shaft and a distal end mounted to the needle body,

wherein the anchor is mounted for deployment from a collapsed configuration to an expanded deployed configuration for engaging and retracting the hollow organ by relative longitudinal translation of the needle body an outer shaft, and

wherein the distal end of the anchor is attached to an outer surface of the needle body such that the sharpened distal tip extends beyond the distal end of the anchor in both the collapsed and the expanded deployed configurations.

2. The surgical instrument of claim **1**, wherein the aperture in the needle body is operatively disposed between the proximal and distal ends of the anchor in both the collapsed and expanded deployed configurations.

3. The surgical instrument of claim **1**, wherein the distal end of the anchor is longitudinally fixed relative to an outside surface of the needle body.

4. The surgical instrument of claim **1**, wherein the anchor is a deployable cage structure.

5. The surgical instrument of claim **4**, wherein the cage structure is spring-biased such that the cage structure is deployed by tension provided in a spring when the cage structure extends beyond the needle body by a predetermined distance.

6. The surgical instrument of claim **4**, wherein the cage structure includes at least one barb configured to extend from the cage structure when the cage structure is in the deployed configuration.

7. The surgical instrument of claim **6**, wherein barb is distally directed to facilitate reinsertion of the cage structure into a lumen of the needle body.

8. The surgical instrument of claim **6**, wherein the at least one barb is proximally directed to facilitate engagement thereof with an inner wall of the hollow organ.

9. The surgical instrument of claim **8**, wherein the cage is configured so that the at least one barb is substantially parallel to the needle body and surrounding portions of the cage in the collapsed configuration.

10. The surgical instrument of claim **4**, wherein the cage structure is provided with at least one fenestration to facilitate bending manipulation of the cage.

11. The surgical instrument of claim **4**, wherein the cage structure is provided with a plurality of legs, symmetrically arranged about a longitudinal axis of the surgical instrument.

12. The surgical instrument of claim **4**, wherein the cage structure includes a plurality of nested cages to permit flexibility of the cage.

13. The surgical instrument of claim **1**, wherein the anchor is a deployable wire structure.

14. The surgical instrument of claim **1**, wherein the anchor includes a distal anchor portion and a proximal anchor portion adapted and configured to engage inner and outer surfaces of the hollow organ, respectively.

15. The surgical instrument of claim **14**, wherein the distal anchor portion and the proximal anchor portion are longitudinally spaced apart by a distance sufficient to permit engagement of a wall of the hollow organ.

16. The surgical instrument of claim **14**, wherein the distal anchor portion and a proximal anchor portion are rotationally offset from one another by about 90 degrees, with respect to a longitudinal axis of the surgical instrument.

17. The surgical instrument of claim **14**, wherein the distal anchor portion and the proximal anchor portion are of substantially the same configuration.

18. The surgical instrument of claim **1**, further comprising a deployable tip protector to inhibit unintentional injury by the sharpened distal tip of the needle body.

19. The surgical instrument of claim **18**, wherein the deployable tip protector is a translatable sheath adapted and configured to be deployed over the sharpened distal tip of the needle body.

20. The surgical instrument of claim **18**, wherein the deployable tip protector is a translatable plug adapted and configured to be deployed from within a lumen of the needle body.

21. The surgical instrument of claim **20**, wherein the plug is adapted and configured to extend distally beyond the sharpened distal tip of the needle body, to inhibit piercing of a structure by the needle body, when in a deployed position.

22. The surgical instrument of claim **1**, wherein the aperture is provided at the distal end of the body.

23. The surgical instrument of claim **1**, wherein the aperture is provided in a distal end portion of a sidewall of the body.

24. The surgical instrument of claim **1**, wherein the anchor is formed at least in part from one of a shape-memory alloy and a stainless steel.

25. The surgical instrument of claim **1**, when in the anchor is formed at least in part by laser cutting.

26. The surgical instrument of claim **1**, wherein an outer diameter of the needle body is about 2 mm.

27. The surgical instrument of claim **1**, wherein the anchor is configured such that, in the deployed configuration, a width, measured transverse to a longitudinal axis thereof, is a maximum of about eight times that of a width in the collapsed configuration, measured transverse to the longitudinal axis thereof.

28. The surgical instrument of claim **1**, wherein the needle body is provided with a sharpened end surface angled at about 15 degrees with respect to a longitudinal axis of the needle body.

29. The surgical instrument of claim **1**, further comprising a handle in connection therewith, to facilitate manipulation of the surgical instrument.

30. The surgical instrument of claim **1**, wherein the needle body includes a side surface having a plurality of apertures for aspiration.

31. A method of retracting a hollow organ comprising the steps of:

providing the surgical instrument of claim **1**,

inserting the needle body of the surgical instrument through an abdominal wall of a patient;

inserting the needle body of the surgical instrument through a wall of the hollow organ;

aspirating the contents from the hollow organ;

deploying the first anchor of the surgical instrument within the hollow organ, to engage an inner surface of the hollow organ; and

retracting the hollow organ.

32. The method of claim **31**, further comprising the step of: deploying a second anchor portion of the surgical instrument outside the hollow organ to engage an outer surface of the hollow organ.

33. A surgical instrument for laparoscopic procedures, adapted and configured to aspirate and retract a gallbladder, comprising:

means for aspirating contents from a gallbladder, the means for aspirating including an aperture defined by a needle of the surgical instrument, the needle including a sharpened distal tip; and

means for engaging and retracting and stabilizing the gallbladder, the means for engaging and retracting and stabilizing including an outer shaft longitudinally translatable relative to the needle, an anchor mounted to the needle and the outer shaft such that distal longitudinal translation of the outer shaft relative to the needle moves the anchor from a collapsed configuration to an expanded deployed configuration for engaging and retracting and stabilizing the gallbladder, the anchor having a proximal end mounted to the outer shaft and a distal end mounted to the needle,

wherein the distal end of the anchor is attached to an outer surface of the needle such that the sharpened distal tip extends beyond the distal end of the anchor in both the collapsed and the expanded deployed configurations.

34. A surgical instrument manufactured by a process comprising the steps of:

providing a tubular needle with a lumen extending therethrough and a sharpened distal tip;

machining a deployable anchor;

machining and mounting an outer shaft concentrically and radially outward of the needle body such that the tubular needle and outer shaft are longitudinally translatable relative to one another;

mounting the deployable anchor to the needle and the outer shaft such that relative longitudinal translation of the outer shaft and needle causes the anchor to move between a radially collapsed configuration and an expanded deployed configuration

wherein the mounting the deployable anchor includes attaching a distal end of the anchor to an outer surface of the needle such that the sharpened distal tip extends beyond the distal end of the anchor in both the radially collapsed and the expanded deployed configurations.

* * * * *